

Designation Run Report

# Kelly, Patrick - Plaintiffs' Submission

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Kelly, Patrick 05-10-2019

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Plaintiffs Affirmative Designations 01:11:55

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Defense Completeness Counters 00:03:53

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Total Time 01:15:48



## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
31:10 - 31:15	<b>Kelly, Patrick 05-10-2019 (00:00:11)</b>	PK03.1
	31:10 Q. Okay. So you understand	
	31:11 that you're here in your individual	
	31:12 capacity but you're also here as the	
	31:13 official representative of HDA with	
	31:14 respect to certain topics, correct?	
	31:15 A. I understand that, yes.	
36:6 - 37:1	<b>Kelly, Patrick 05-10-2019 (00:00:35)</b>	PK03.2
	36:6 Q. Okay. Who is Anita Ducca?	
	36:7 A. Anita Ducca is the senior	
	36:8 vice president of regulatory affairs for	
	36:9 Healthcare Distribution Alliance.	
	36:10 Q. She reports to you?	
	36:11 A. She does.	
	36:12 Q. How long have you been with	
	36:13 the HDA?	
	36:14 A. I joined in January of 2011.	
	36:15 Q. The HDA is an organization	
	36:16 that acts on behalf of its members,	
	36:17 correct?	
	36:18 A. That's correct.	
	36:19 Q. Your members include the,	
	36:20 what we refer to in the case as the big	
	36:21 three distributors, Cardinal Health,	
	36:22 AmerisourceBergen, and McKesson; is that	
	36:23 correct?	
	36:24 A. In addition to -- in	
	37:1 addition to 29 other companies, yes.	
38:20 - 39:12	<b>Kelly, Patrick 05-10-2019 (00:00:23)</b>	PK03.3
	38:20 Q. Okay. You have a board,	
	38:21 correct?	
	38:22 A. We do.	
	38:23 Q. The board membership always	
	38:24 includes members from the big three,	
	39:1 AmerisourceBergen, McKesson, and Cardinal	
	39:2 Health, correct?	
	39:3 A. In addition to the 29 other	
	39:4 members, yes.	
	39:5 Q. Okay. But the board always	
	39:6 has somebody from those companies on it?	

## PK03-Kelly, Patrick - Plaintiffs' Submission

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39:7	A. That's correct.	
39:8	Q. And then there's an	
39:9	executive committee as well, correct?	
39:10	A. That is correct.	
39:11	Q. And what's the makeup of the	
39:12	executive committee?	
39:16 - 40:3	<b>Kelly, Patrick 05-10-2019 (00:00:22)</b>	<b>PK03.4</b>
39:16	THE WITNESS: The executive	
39:17	committee is seven members, three	
39:18	members from the big three,	
39:19	AmerisourceBergen, McKesson, and	
39:20	Cardinal have a standing position	
39:21	on the executive committee.	
39:22	And then there are four	
39:23	other positions that are other	
39:24	member companies that filter	
40:1	through kind of as -- as positions	
40:2	become available, retirement, and	
40:3	companies move on.	
40:5 - 40:8	<b>Kelly, Patrick 05-10-2019 (00:00:05)</b>	<b>PK03.5</b>
40:5	Q. The HDA doesn't take any	
40:6	action without the approval of either the	
40:7	executive committee or its board,	
40:8	correct?	
40:11 - 40:21	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b>	<b>PK03.6</b>
40:11	THE WITNESS: Again, it	
40:12	depends -- it depends on what you	
40:13	mean by action. I mean, there are	
40:14	certain things that rise to the	
40:15	level of the board that require	
40:16	their approval of expenditures, et	
40:17	cetera. But there are day-to-day	
40:18	operations that do not require	
40:19	approval of the board that we	
40:20	undertake on behalf of the	
40:21	membership.	
42:17 - 42:21	<b>Kelly, Patrick 05-10-2019 (00:00:12)</b>	<b>PK03.7</b>
42:17	Q. How about engaging with	
42:18	members of Congress, is HDA going to	
42:19	reach out to members of Congress without	

## PK03-Kelly, Patrick - Plaintiffs' Submission

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42:24 - 43:19	<p>42:20 approval from the board or the executive 42:21 committee?</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:34)</b></p> <p>42:24 THE WITNESS: We engage 43:1 with, I mean, members of Congress 43:2 on a weekly basis through a 43:3 variety of fronts depending on 43:4 committee hearings or fundraisers 43:5 that we attend from our political 43:6 action committee. 43:7 And again, all of those 43:8 are -- we communicate those to the 43:9 board, but they are not decisions 43:10 that need to be made by the board 43:11 before HDA staff engage. 43:12 BY MR. PIFKO: 43:13 Q. Okay. So then that was 43:14 going to be my other question. When you 43:15 do communicate and interact with federal 43:16 agencies or state agencies or members of 43:17 Congress or any elected officials, you 43:18 always report back to either the board or 43:19 the executive committee, correct?</p>	PK03.8
43:22 - 44:3	<p><b>Kelly, Patrick 05-10-2019 (00:00:05)</b></p> <p>43:22 THE WITNESS: If it's -- if 43:23 it's relevant for board 43:24 consideration, yes. 44:1 BY MR. PIFKO: 44:2 Q. Or the executive committee? 44:3 A. Or the executive committee.</p>	PK03.9
44:4 - 44:9	<p><b>Kelly, Patrick 05-10-2019 (00:00:16)</b></p> <p>44:4 Q. So going back to Exhibit 2. 44:5 You -- Ms. Ducca says that "per your 44:6 request, attached is a chronology of 44:7 interactions with the DEA." 44:8 Do you see that? 44:9 A. I do.</p>	PK03.10
44:10 - 44:16	<p><b>Kelly, Patrick 05-10-2019 (00:00:16)</b></p> <p>44:10 Q. You requested that she put 44:11 together a chronology of HDA/DEA</p>	PK03.162

## PK03-Kelly, Patrick - Plaintiffs' Submission

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44:12 interactions in 2016? 44:13 A. I don't know that I 44:14 requested that she put it together. I 44:15 know that she had been basically 44:16 compiling the interactions.	<b>Kelly, Patrick 05-10-2019 (00:00:08)</b>	PK03.11
44:17 Q. Okay. So she had been 44:18 compiling them contemporaneously with as 44:19 they occurred? 44:20 A. Right. 44:21 Q. And then you asked her at 44:22 this point for a copy of what she had 44:23 prepared? 44:24 A. Yes.	<b>Kelly, Patrick 05-10-2019 (00:00:13)</b>	PK03.163
45:1 Q. The -- what follows after 45:2 the cover e-mail, this chronology, this 45:3 is accurate to the best of your 45:4 knowledge? 45:5 A. To the best of my knowledge, 45:6 yes. Some of it does take place before I 45:7 joined the organization.	<b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.12
45:8 Q. But you're familiar with 45:9 these events? 45:10 A. I am.	<b>Kelly, Patrick 05-10-2019 (00:00:12)</b>	PK03.13
45:16 Q. Okay. We're going to be 45:17 talking about several of these, starting, 45:18 as I talked about with Topic 4, the 45:19 industry compliance guidelines. You're 45:20 familiar with those? 45:21 A. I am. 45:22 Q. And you're familiar with the 45:23 history of those? 45:24 A. Yes.	<b>Kelly, Patrick 05-10-2019 (00:00:04)</b>	PK03.14

## PK03-Kelly, Patrick - Plaintiffs' Submission

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50:2 - 50:3	50:1 yes. <b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.15
50:8 - 50:13	50:2 Q. I'm handing you what's been 50:3 marked as Exhibit 3. <b>Kelly, Patrick 05-10-2019 (00:00:21)</b>	PK03.16
50:17 - 50:18	50:8 Q. It's an e-mail from Pam 50:9 Ritter at the HDA dated Wednesday, May 50:10 30th, 2007, to a whole host members of 50:11 the pharmaceutical industry. It's 50:12 Bates-labeled HSI_MDL_00620224 through 50:13 228. <b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.164
50:19 - 51:10	50:17 Q. Take a moment to review that 50:18 and let me know when you're ready. <b>Kelly, Patrick 05-10-2019 (00:00:23)</b>	PK03.175
50:22 - 51:10	50:19 Do you know who Pam Ritter 50:20 is? 50:21 A. Yes. 50:22 Q. Who is Pam Ritter? 50:23 A. Pam Ritter was the 50:24 administrative assistant for the 51:1 department -- the government affairs 51:2 department at HDA. 51:3 Q. Okay. What's the government 51:4 affairs department? 51:5 A. The government affairs 51:6 department is the department that I run 51:7 within the organization. It is the 51:8 department that houses our regulatory 51:9 affairs, federal government affairs, and 51:10 state government affairs teams. <b>Kelly, Patrick 05-10-2019 (00:00:19)</b>	PK03.17
	50:22 Q. Who is Pam Ritter? 50:23 A. Pam Ritter was the 50:24 administrative assistant for the 51:1 department -- the government affairs 51:2 department at HDA. 51:3 Q. Okay. What's the government 51:4 affairs department? 51:5 A. The government affairs	

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51:6 department is the department that I run  
 51:7 within the organization. It is the  
 51:8 department that houses our regulatory  
 51:9 affairs, federal government affairs, and  
 51:10 state government affairs teams.

51:18 - 51:24

**Kelly, Patrick 05-10-2019 (00:00:06)**

PK03.18

51:18 Q. you're  
 51:19 obviously are familiar with something  
 51:20 called the regulatory affairs committee?  
 51:21 A. I am, yes.  
 51:22 Q. That's a committee that's  
 51:23 within your purview?

51:24 A. Yes, it is.

52:4 - 52:13

**Kelly, Patrick 05-10-2019 (00:00:12)**

PK03.19

52:4 Q. But that -- at all  
 52:5 times, that includes AmerisourceBergen,  
 52:6 McKesson and Cardinal Health, correct?  
 52:7 A. If they are able to  
 52:8 participate, yes.  
 52:9 Q. Okay. But they're standing  
 52:10 members of that committee?  
 52:11 A. They -- yeah, as are the  
 52:12 rest of the members of the association,  
 52:13 yes.

53:7 - 54:2

**Kelly, Patrick 05-10-2019 (00:00:52)**

PK03.20

53:7 Q. Okay. And it says the  
 53:8 purpose of the call is -- I'm going to  
 53:9 quote here, it says, "At the May 17th --  
 53:10 which is 2007. "At the May 17th  
 53:11 executive committee, there was a  
 53:12 discussion about recent DEA activities to  
 53:13 involve wholesale distributors in efforts  
 53:14 to prevent diversion."  
 53:15 Do you see that?  
 53:16 A. I do.  
 53:17 Q. Did I read that correctly?  
 53:18 A. Yes.  
 53:19 Q. Okay. And as a result of  
 53:20 what HDA is calling recent DEA activities  
 53:21 to involve wholesale distributors in

## PK03-Kelly, Patrick - Plaintiffs' Submission

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53:22 efforts to prevent diversion, the  
 53:23 executive committee requested that HDA  
 53:24 become involved and come up with some  
 54:1 strategies to interact with DEA, correct?  
 54:2 A. Yes.

66:13 - 66:18

**Kelly, Patrick 05-10-2019 (00:00:16)**

PK03.165

66:13 Q. I'm handing you what's  
 66:14 marked as Exhibit 5. It is a single-page  
 66:15 e-mail. It's Bates-labeled  
 66:16 HDA\_MDL\_000213427. Take a minute to  
 66:17 review it and let me know when you're  
 66:18 ready.

66:19 - 66:19

**Kelly, Patrick 05-10-2019 (00:00:01)**

PK03.176

66:19 A. Okay.

66:20 - 68:1

**Kelly, Patrick 05-10-2019 (00:00:56)**

PK03.21

66:20 Q. There's two e-mails in here,  
 66:21 only really one of substance. The  
 66:22 substantive e-mail is from John Gray  
 66:23 to -- is it Paul Julian dated Tuesday,  
 66:24 October 30th, 2007, and then John Gray  
 67:1 forwards that to Scott Melville.  
 67:2 Do you see that?  
 67:3 A. I do.  
 67:4 Q. And the subject is HDMA  
 67:5 board meeting.  
 67:6 Do you see that?  
 67:7 A. Yes.  
 67:8 Q. Okay. Who's John Gray?  
 67:9 A. John Gray is the president  
 67:10 and CEO of HDA.  
 67:11 Q. To your knowledge, how long  
 67:12 has he been in that role?  
 67:13 A. Since 2004 I believe, maybe  
 67:14 '3.  
 67:15 Q. So at this time, he was  
 67:16 president and CEO of HDA?  
 67:17 A. HDMA at the time, yes.  
 67:18 Q. Okay. And do you know who  
 67:19 Paul Julian is?  
 67:20 A. Paul Julian was the board

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68:7 - 70:5

67:21 member that was tasked to basically  
67:22 represent McKesson on the HDA Board of  
67:23 Directors.

67:24 Q. Okay. And then John Gray  
68:1 forwards this exchange to Scott Melville.

**Kelly, Patrick 05-10-2019 (00:01:08)**

PK03.22

68:7 Q. Who is he?

68:8 A. Scott Melville was the  
68:9 former head of the government affairs  
68:10 department at HDA.

68:11 Q. Is Scott Melville still  
68:12 there?

68:13 A. He is not.

68:14 Q. So did you take over his  
68:15 position?

68:16 A. I did.

68:17 Q. And Anita Ducca reported to  
68:18 him at this time?

68:19 A. She did.

68:20 Q. So John Gray writes to Paul.

68:21 He says, among other things, if you are  
68:22 -- are you there?

68:23 A. I am.

68:24 Q. "The DEA issue concerning  
69:1 the recent surge in DEA enforcement  
69:2 around suspicious orders and methadone  
69:3 was moved to the top of the HDMA priority  
69:4 list."

69:5 Do you see that?

69:6 A. I do.

69:7 Q. Do you agree that the DEA  
69:8 issue concerning what they call -- he  
69:9 calls a recent surge in enforcement  
69:10 around suspicious order was a top  
69:11 priority of the HDMA at the time?

69:12 A. I do.

69:13 Q. He says, "The board wants  
69:14 the association" -- that means the HDA,  
69:15 correct?

69:16 A. Yes.

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	69:17 Q. -- "to quickly develop a 69:18 plan to deal with and work with the DEA 69:19 as necessary." 69:20 Do you see that? 69:21 A. I do. 69:22 Q. So there was discussions to 69:23 develop a plan to deal with the DEA at 69:24 this time, correct? 70:1 A. Yes. 70:2 Q. In response to this recent 70:3 surge in enforcement around suspicious 70:4 orders, correct? 70:5 A. Yes.	
72:14 - 72:23	<b>Kelly, Patrick 05-10-2019 (00:00:51)</b> 72:14 Q. I'm handing you what's been 72:15 marked as Exhibit 6. Exhibit 6 is a 72:16 PowerPoint presentation Bates-labeled 72:17 HDA_MDL_000143030 through 043 or 143043. 72:18 According to the metadata, 72:19 which is attached on the first page of 72:20 this document, it was last modified 72:21 December 10th, 2007, and the file name 72:22 was slide for -- "Slides for Packaging 72:23 Call, 12/10/2007."	PK03.23
73:7 - 73:9	<b>Kelly, Patrick 05-10-2019 (00:00:05)</b> 73:7 Q. Are you familiar with the 73:8 format of these slides? Is that the HDMA 73:9 logo on the bottom?	PK03.24
73:12 - 73:21	<b>Kelly, Patrick 05-10-2019 (00:00:16)</b> 73:12 THE WITNESS: I -- I am -- 73:13 yes, that is a common slide format 73:14 that we have used. 73:15 BY MR. PIFKO: 73:16 Q. And when you have these 73:17 conference calls, sometimes they have 73:18 webinars or you share the PowerPoint 73:19 presentations with people and you go 73:20 through them when you have a call? 73:21 A. Sometimes.	PK03.25
74:14 - 75:18	<b>Kelly, Patrick 05-10-2019 (00:00:44)</b>	PK03.26

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74:14 Q. This was produced by HDMA,  
74:15 do you have any reason to dispute the  
74:16 authenticity of this document?

74:17 A. I do not.

74:18 Q. The first slide here says,  
74:19 "Tomorrow's Outcome?"

74:20 Do you see that?

74:21 A. Yes.

74:22 Q. "What are the impacts on our  
74:23 members?"

74:24 Do you see that?

75:1 A. I do.

75:2 Q. "Can we identify common  
75:3 themes and problems?"

75:4 Do you see that?

75:5 A. I do.

75:6 Q. And then it says, "Should  
75:7 we," and it's got some bullet points.

75:8 Do you see that?

75:9 A. Yes.

75:10 Q. One of them is, "Challenge  
75:11 the DEA."

75:12 Do you see that?

75:13 A. Yes.

75:14 Q. At this time in late 2007 in  
75:15 response to this surge in enforcement  
75:16 activity, one of the strategies HDMA and  
75:17 its members were considering was to  
75:18 challenge the DEA, correct?

75:21 - 77:3

**Kelly, Patrick 05-10-2019 (00:00:45)**

PK03.27

75:21 THE WITNESS: Yes.

75:22 BY MR. PIFKO:

75:23 Q. It says on the next page,  
75:24 "DEA will be here to describe their  
76:1 expectations."

76:2 Do you see that?

76:3 A. I do.

76:4 Q. And it -- it gives some  
76:5 examples of what HDA understands their  
76:6 expectations to be at this time.

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	76:7 Do you see that?	
	76:8 A. Yes.	
	76:9 Q. "Know your customer better,"	
	76:10 correct?	
	76:11 A. That's what it says.	
	76:12 Q. "Have processes/controls in	
	76:13 place to detect suspicious orders,"	
	76:14 correct?	
	76:15 A. Yes.	
	76:16 Q. "Stop 'suspicious' order	
	76:17 sales" -- underlined -- "before	
	76:18 shipment."	
	76:19 Do you see that?	
	76:20 A. Yes.	
	76:21 Q. That's correct?	
	76:22 A. Yes.	
	76:23 Q. "Less interested in reports	
	76:24 after shipment."	
	77:1 Do you see that?	
	77:2 A. Yes. That's what it says,	
	77:3 yes.	
77:4 - 77:18	<b>Kelly, Patrick 05-10-2019 (00:00:33)</b>	PK03.177
	77:4 Q. Turn to the third page of	
	77:5 the document, of the -- the slides. So	
	77:6 it's technically the fourth page of the	
	77:7 document. "Suspicious orders - policy	
	77:8 questions" is the heading of the slide.	
	77:9 Do you see that?	
	77:10 A. I do.	
	77:11 Q. Halfway down the slide it	
	77:12 says, "Should we support DEA's efforts?"	
	77:13 Do you see that?	
	77:14 A. Yes.	
	77:15 Q. So there are some questions	
	77:16 about whether HDMA and its members were	
	77:17 going to support DEA's efforts, correct?	
	77:18 A. Yes.	
78:1 - 78:20	<b>Kelly, Patrick 05-10-2019 (00:00:32)</b>	PK03.28
	78:1 Q. One of the bullet points is,	
	78:2 "Develop business practices," which is --	

## PK03-Kelly, Patrick - Plaintiffs' Submission

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78:3 business practices is in quote.

78:4 Do you see that?

78:5 A. I do.

78:6 Q. Do you now understand what

78:7 that refers to?

78:8 A. I -- I think what it led to,

78:9 yes.

78:10 Q. The industry compliance

78:11 guidelines, correct?

78:12 A. Yes.

78:13 Q. And then it says,

78:14 "Alternatively do we want to challenge

78:15 DEA's expectations?"

78:16 Do you see that?

78:17 A. Yes.

78:18 Q. And that was something else

78:19 HDMA and its members were considering at

78:20 this time, correct?

78:22 - 79:13

**Kelly, Patrick 05-10-2019 (00:00:18)**

PK03.29

78:22 THE WITNESS: Again, I think

78:23 there was a variety of

78:24 considerations going on at the

79:1 time, yes.

79:2 BY MR. PIFKO:

79:3 Q. But this was one of them,

79:4 correct?

79:5 A. According to this, yes.

79:6 Q. Again, it says, "What are

79:7 our legal options?"

79:8 Do you see that?

79:9 A. I do.

79:10 Q. So there were some

79:11 evaluations of what legal strategies can

79:12 be employed to challenge the DEA's

79:13 expectations?

79:16 - 79:18

**Kelly, Patrick 05-10-2019 (00:00:03)**

PK03.30

79:16 THE WITNESS: Again, I think

79:17 those considerations were being

79:18 discussed.

82:2 - 82:10

**Kelly, Patrick 05-10-2019 (00:00:39)**

PK03.31

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
82:2 - 83:7	<p>82:2 Q. I'm handing you a single</p> <p>82:3 page e-mail from Ms. Ducca marked as</p> <p>82:4 Exhibit 8. It's Bates-labeled</p> <p>82:5 CAH_MDL2804_012489160.</p> <p>82:6 It's from Ms. Ducca dated</p> <p>82:7 October 28, 2011, to Cardinal Health's</p> <p>82:8 Robert Giacalone.</p> <p>82:9 A. Giacalone.</p> <p>82:10 Q. Giacalone.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:32)</b></p> <p>82:15 Q. So in it, Ms. Ducca is</p> <p>82:16 explaining the history of some of the</p> <p>82:17 negotiations and discussions regarding</p> <p>82:18 the industry compliance guidelines,</p> <p>82:19 correct?</p> <p>82:20 A. Yes.</p> <p>82:21 Q. Okay. And you could see</p> <p>82:22 from the e-mail there are several</p> <p>82:23 attachments, if you look on the header.</p> <p>82:24 A. I see that.</p> <p>83:1 Q. Okay. And then she says,</p> <p>83:2 there's there -- there were three</p> <p>83:3 meetings with DEA on the ICG guidelines,</p> <p>83:4 one, April 15, 2008, one June 4, 2008,</p> <p>83:5 one in September 2008.</p> <p>83:6 Do you see that?</p> <p>83:7 A. I do.</p>	PK03.32
84:15 - 84:21	<p><b>Kelly, Patrick 05-10-2019 (00:00:11)</b></p> <p>84:15 Q. And then she says, "Also</p> <p>84:16 included is a summary of a meeting HDMA</p> <p>84:17 had with DEA in September of '07 just to</p> <p>84:18 ask them what was going on with their</p> <p>84:19 meetings with distributors."</p> <p>84:20 Do you see that?</p> <p>84:21 A. I do.</p>	PK03.34
85:2 - 85:8	<p><b>Kelly, Patrick 05-10-2019 (00:00:30)</b></p> <p>85:2 Q. I'm going to hand you some</p> <p>85:3 of the attachments, starting with her</p> <p>85:4 summary of the September 7th, 2007,</p> <p>85:5 meeting with DEA. Exhibit 9.</p>	PK03.35

## PK03-Kelly, Patrick - Plaintiffs' Submission

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85:12 - 85:20	<p>85:6 This is a two-page document,  85:7 Exhibit 9, Bates-labeled  85:8 CAH_MDL2804_02489199 through 200.  <b>Kelly, Patrick 05-10-2019 (00:00:18)</b></p> <p>85:12 Q. This was the meeting that  85:13 was held in response to the request that  85:14 HDA made on July 25th, 2007, correct?  85:15 This is a summary of that meeting,  85:16 correct?  85:17 A. I believe so, yes.  85:18 Q. Which is referred to in  85:19 Exhibit 7, right? That's the letter.  85:20 A. Yes.</p>	PK03.36
86:5 - 86:13	<p><b>Kelly, Patrick 05-10-2019 (00:00:19)</b></p> <p>86:5 Q. So this meeting included,  86:6 from HDMA, Scott Melville, Anita Ducca,  86:7 and David Durkin, who's outside counsel  86:8 for HDA, correct?  86:9 A. Correct.  86:10 Q. And DEA attendees included  86:11 Mark Caverly, Cathy Gallagher, Mike  86:12 Mapes, and Lisa Sullivan, correct?  86:13 A. Correct.</p>	PK03.37
86:22 - 87:6	<p><b>Kelly, Patrick 05-10-2019 (00:00:21)</b></p> <p>86:22 Q. In her summary section on  86:23 the first page -- so one of the things  86:24 that HDA requested in the July 25th,  87:1 2007, letter, Exhibit 7, was to  87:2 understand the -- what we called the  87:3 distributor initiative. And there is  87:4 some discussion here that Mike Mapes  87:5 provided about that.  87:6 Do you see that?</p>	PK03.38
87:9 - 91:15	<p><b>Kelly, Patrick 05-10-2019 (00:02:58)</b></p> <p>87:9 THE WITNESS: Yes.  87:10 BY MR. PIFKO:  87:11 Q. Okay. So the summary that  87:12 Ms. Ducca prepared says that, "Mr. Mapes  87:13 noted that DEA had met with approximately  87:14 15 to 20 wholesale distributors one on</p>	PK03.39

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87:15 one. They had prioritized who to meet  
87:16 with on a combination of wholesale  
87:17 distributor sales volume and tracing back  
87:18 to where they felt the source of products  
87:19 for illicit internet pharmacies were  
87:20 located."

87:21 Do you see that?

87:22 A. I do.

87:23 Q. Do you have any reason to  
87:24 dispute that that's what DEA told HDMA  
88:1 during this meeting?

88:2 A. I do not.

88:3 Q. Then she says, key takeaways  
88:4 from the meetings are -- from the meeting  
88:5 were, first bullet point, "DEA's policy  
88:6 was to expect more than just reporting  
88:7 suspicious orders."

88:8 Do you see that?

88:9 A. I do.

88:10 Q. Second bullet point, "Simply  
88:11 complying with the 'suspicious orders'  
88:12 regulatory requirement does not mean, in  
88:13 the agency's view, that the registrant is  
88:14 making" -- "maintaining an effective  
88:15 program to detect and prevention  
88:16 diversion."

88:17 Do you see that?

88:18 A. I do.

88:19 Q. Did I read that correctly?

88:20 A. You did.

88:21 Q. Third bullet point, "DEA  
88:22 indicated that they did not have the  
88:23 resources to inspect every pharmacy;  
88:24 therefore, it was important for the  
89:1 distributor to 'know their customers.'"

89:2 Do you see that?

89:3 A. I do.

89:4 Q. Do you have an -- any reason  
89:5 to dispute that these were key takeaways  
89:6 from the meeting?

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89:7 A. I do not.

89:8 Q. Then she has under her

89:9 heading additional points DEA made

89:10 included.

89:11 Do you see that?

89:12 A. Yes.

89:13 Q. The second one says, "DEA

89:14 provided examples of what a

89:15 distributor" -- "a wholesale distributor

89:16 should do to 'know their customers' and

89:17 what to look for."

89:18 Do you see that?

89:19 A. I do.

89:20 Q. Do you have any reason to

89:21 dispute that DEA during this meeting

89:22 provided examples of what distributors

89:23 should do to know their customers?

89:24 A. I do not.

90:1 Q. Going to the second page,

90:2 second-to-last bullet point at the top of

90:3 that page, "DEA also indicated that they

90:4 were not going to make a decision for the

90:5 wholesale distributor as to when an order

90:6 was suspicious."

90:7 Do you see that?

90:8 A. I do.

90:9 Q. "They feel this is up to the

90:10 distributor."

90:11 Do you see that?

90:12 A. I do.

90:13 Q. Do you have any reason to

90:14 dispute that this is what DEA told HDMA

90:15 during this meeting?

90:16 A. I do not.

90:17 Q. Last bullet point. "DEA

90:18 suggested that distributors should check

90:19 on the pharmacies' prescribing

90:20 physicians. They pointed to some states

90:21 having online systems by which a

90:22 distributor could check to see if a

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	90:23 prescribing physician had a valid DEA 90:24 registration. DEA suggested that 91:1 distributors ask who the doctors are that 91:2 are prescribing, where the pharmacy is 91:3 geographically with respect to its 91:4 prescribing doctors, and the patient 91:5 population." 91:6 Do you see that? 91:7 A. I do. 91:8 Q. Any reason to dispute that 91:9 that's something that DEA told HDMA 91:10 during this meeting? 91:11 A. I do not. 91:12 Q. And per the normal practice, 91:13 HDMA would have communicated this 91:14 information back to its members after the 91:15 meeting occurred, correct?	
91:18 - 91:18	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b>	PK03.40
	91:18 THE WITNESS: Correct.	
91:23 - 91:24	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b>	PK03.166
	91:23 Q. I'm handing you what's 91:24 marked as Exhibit 10. For the record,	
92:1 - 92:2	<b>Kelly, Patrick 05-10-2019 (00:00:19)</b>	PK03.178
	92:1 it's a multiple-page document 92:2 Bates-labeled HDA_MDL_000151104 through	
92:3 - 92:5	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b>	PK03.179
	92:3 151118. Take a minute to review 92:4 Exhibit 10 and let me know when you're 92:5 ready.	
92:17 - 93:6	<b>Kelly, Patrick 05-10-2019 (00:00:29)</b>	PK03.41
	92:17 Q. So as we discussed when we 92:18 looked at Exhibit 3, in response to what 92:19 HDMA told its members was a recent DEA 92:20 activities to involve wholesale 92:21 distributors in efforts to prevent 92:22 diversion, HDMA and its members were 92:23 discussing putting together some best 92:24 practices or guidelines concerning 93:1 suspicious orders, correct? 93:2 A. Correct.	

## PK03-Kelly, Patrick - Plaintiffs' Submission

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93:3	Q. And ultimately HDMA and its	
93:4	members decided to move forward with that	
93:5	project, correct?	
93:6	A. Correct.	
108:20 - 109:1	<b>Kelly, Patrick 05-10-2019 (00:00:27)</b>	PK03.42
108:20	Q. I'm handing you what's	
108:21	marked as Exhibit 11. For the record,	
108:22	it's a document, a few pages long, with	
108:23	the heading "NWDA Suspicious Order	
108:24	Monitoring System." It's Bates-labeled	
109:1	CAH_MDL2804_02201910 through 1916.	
109:11 - 109:16	<b>Kelly, Patrick 05-10-2019 (00:00:12)</b>	PK03.43
109:11	So as we know from the other	
109:12	e-mails and discussion on this best	
109:13	practices guidelines issue, the HDA's	
109:14	predecessor had some sort of other	
109:15	suspicious order monitoring guidelines,	
109:16	correct?	
109:23 - 110:1	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b>	PK03.44
109:23	THE WITNESS: Again, I've	
109:24	not seen this before. But I will	
110:1	take you at your word, yes.	
110:15 - 110:22	<b>Kelly, Patrick 05-10-2019 (00:00:14)</b>	PK03.45
110:15	Q. My question is, you agree	
110:16	there were previous guidelines. She	
110:17	makes reference to it in the scope of	
110:18	work here, correct?	
110:19	A. She did make -- I agree she	
110:20	did make a reference to it. And this is	
110:21	an example of those guidelines, I	
110:22	imagine. Yes.	
110:23 - 110:24	<b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.167
110:23	Q. To your knowledge, these are	
110:24	dated around the '80s?	
111:3 - 111:17	<b>Kelly, Patrick 05-10-2019 (00:00:30)</b>	PK03.180
111:3	THE WITNESS: I have -- I	
111:4	have no idea when these are dated.	
111:5	BY MR. PIFKO:	
111:6	Q. Okay. Did you discuss	
111:7	these, or any prior HDA or its	

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	111:8 predecessor entity guidelines in	
	111:9 preparing for depositions with anybody?	
	111:10 A. I have not seen this	
	111:11 document before.	
	111:12 Q. Did you undertake any effort	
	111:13 to familiarize yourself with HDA's prior	
	111:14 suspicious order guidelines in connection	
	111:15 with preparing for this deposition?	
	111:16 A. Other than the ICGs, no,	
	111:17 nothing.	
111:18 - 112:3	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b>	PK03.46
	111:18 Q. NWDA is a predecessor name	
	111:19 for HDA correct?	
	111:20 A. That's correct.	
	111:21 Q. National Wholesale	
	111:22 Druggists' Association, correct?	
	111:23 A. Correct.	
	111:24 Q. Okay. Do you have any	
	112:1 reason to dispute that these are	
	112:2 guidelines put out on suspicious order	
	112:3 monitoring, put out by the NWDA?	
112:6 - 112:7	<b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.47
	112:6 THE WITNESS: I have no	
	112:7 reason to dispute that.	
114:14 - 115:12	<b>Kelly, Patrick 05-10-2019 (00:00:45)</b>	PK03.48
	114:14 Q. Are you aware that your	
	114:15 website currently states that the NWA was	
	114:16 renamed the Healthcare Distribution	
	114:17 Management Association in 2001?	
	114:18 A. I am.	
	114:19 Q. Okay. So if these are from	
	114:20 the NWDA, they would have to be prior to	
	114:21 that date for sure, correct?	
	114:22 A. Yes.	
	114:23 Q. It's got a Section 2,	
	114:24 "Definition Of Suspicious Orders." It	
	115:1 says, "Suspicious orders include orders	
	115:2 of unusual size, orders deviating	
	115:3 substantially from a normal pattern, and	
	115:4 orders of unusual frequency."	

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	115:5 Do you see that?	
	115:6 A. Yes.	
	115:7 Q. Is that consistent with what	
	115:8 your understanding of what is stated in	
	115:9 the regulations about the definition of	
	115:10 suspicious order?	
	115:11 A. That is all that is stated	
	115:12 in -- in the regulations, yes.	
115:23 - 116:3	<b>Kelly, Patrick 05-10-2019 (00:00:06)</b>	PK03.49
	115:23 Q. It says, "Single orders of	
	115:24 unusual size or deviation must be	
	116:1 reported immediately."	
	116:2 Do you see that?	
	116:3 A. I do.	
116:15 - 117:6	<b>Kelly, Patrick 05-10-2019 (00:00:24)</b>	PK03.50
	116:15 Q. Okay. Then it says here,	
	116:16 "The submission of a monthly printout of	
	116:17 after-the-fact sales will not relieve a	
	116:18 registrant from the responsibility of	
	116:19 reporting these single excessive or	
	116:20 suspicious orders."	
	116:21 Did I read that correctly?	
	116:22 A. You did.	
	116:23 Q. Then it says, "DEA has	
	116:24 interpreted 'orders'" -- the word orders	
	117:1 is in quotes -- "to mean prior to	
	117:2 shipment."	
	117:3 Do you see that?	
	117:4 A. I do.	
	117:5 Q. Did I read that correctly?	
	117:6 A. You did.	
117:7 - 117:9	<b>Kelly, Patrick 05-10-2019 (00:00:08)</b>	PK03.168
	117:7 Q. So do you understand this to	
	117:8 be saying that an order has to be	
	117:9 identified before shipping it?	
117:13 - 117:23	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b>	PK03.193
	117:13 THE WITNESS: Again, I see	
	117:14 what it says here on paper. But	
	117:15 again I'm not an attorney. I'm	
	117:16 not exactly sure what the practice	

## PK03-Kelly, Patrick - Plaintiffs' Submission

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117:17	would require.	
117:18	BY MR. PIFKO:	
117:19	Q. Okay. All I'm asking you is	
117:20	what you understand this document to be	
117:21	saying. You understand it to be saying	
117:22	that an order needs to be identified and	
117:23	reported prior to shipment.	
118:3 - 118:9	<b>Kelly, Patrick 05-10-2019 (00:00:05)</b>	PK03.192
118:3	THE WITNESS: I -- I can	
118:4	read what -- what the document	
118:5	says, yes.	
118:6	BY MR. PIFKO:	
118:7	Q. Is that -- is that what your	
118:8	understanding of the document is? That's	
118:9	all I'm asking.	
118:15 - 119:1	<b>Kelly, Patrick 05-10-2019 (00:00:11)</b>	PK03.191
118:15	THE WITNESS: Again, the	
118:16	document says what it says and I	
118:17	can read what it says.	
118:18	BY MR. PIFKO:	
118:19	Q. Okay. But you have English	
118:20	comprehension. You understand when you	
118:21	read something, right?	
118:22	A. I -- I do have English	
118:23	comprehension.	
118:24	Q. Okay. So all I'm asking you	
119:1	is what you understand this to be saying.	
119:4 - 119:7	<b>Kelly, Patrick 05-10-2019 (00:00:04)</b>	PK03.190
119:4	THE WITNESS: I understand	
119:5	it says, verbatim, DEA has	
119:6	interpreted orders to mean prior	
119:7	to shipment.	
119:9 - 119:13	<b>Kelly, Patrick 05-10-2019 (00:00:09)</b>	PK03.51
119:9	Q. Okay. And so do you	
119:10	understand that to mean in the context of	
119:11	this other language in the paragraph	
119:12	here, that that means an order has to be	
119:13	reported prior to being shipped?	
119:17 - 119:19	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b>	PK03.52
119:17	THE WITNESS: Again, that's	

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186:8 - 186:11	<p>119:18 what it says. That's what I would 119:19 understand it to mean.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:32)</b></p> <p>186:8 Q. I'm handing you what's 186:9 marked as Exhibit 19. This is another 186:10 e-mail from Ms. Ducca Bates-labeled 186:11 HDA_MDL_000148603 to 148633.</p>	PK03.53
190:11 - 191:2	<p><b>Kelly, Patrick 05-10-2019 (00:00:31)</b></p> <p>190:11 Q. Okay. And so one of the 190:12 things in the first paragraph, it says, 190:13 is that, at the bottom of that first full 190:14 paragraph, it's talking about these 190:15 guidelines. It says, "They have been 190:16 prepared in recognition of the growing 190:17 problem of misuse of controlled 190:18 substances and the key role distributors 190:19 play within the prescription drug supply 190:20 chain." 190:21 Did I read that correctly? 190:22 A. You did. 190:23 Q. Okay. And so is that 190:24 consistent with what your understanding 191:1 of the background of how these were 191:2 prepared?</p>	PK03.54
191:5 - 191:11	<p><b>Kelly, Patrick 05-10-2019 (00:00:12)</b></p> <p>191:5 THE WITNESS: Yes, that's 191:6 what I understand it to be. 191:7 BY MR. PIFKO: 191:8 Q. And HDMA and its members 191:9 recognized that there was a growing 191:10 problem of misuse of controlled 191:11 substances at this time?</p>	PK03.55
191:14 - 191:15	<p><b>Kelly, Patrick 05-10-2019 (00:00:02)</b></p> <p>191:14 THE WITNESS: That's what we 191:15 stated here in this introduction.</p>	PK03.56
192:1 - 192:16	<p><b>Kelly, Patrick 05-10-2019 (00:00:28)</b></p> <p>192:1 Q. And then in the next 192:2 paragraph it says, "While drug wholesale 192:3 distributors, like all nongovernmental 192:4 entities, do not have investigative</p>	PK03.57

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	<p>192:5 powers and resources to guarantee that</p> <p>192:6 certain products will not reach illicit</p> <p>192:7 or illegal markets, they are uniquely</p> <p>192:8 situated to perform due diligence in</p> <p>192:9 order to help support the security of the</p> <p>192:10 controlled substances distribution</p> <p>192:11 system."</p> <p>192:12 Did I read that correctly?</p> <p>192:13 A. You did.</p> <p>192:14 Q. That was another thing that</p> <p>192:15 HDA and its members recognized at this</p> <p>192:16 time, correct?</p>	
192:19 - 193:18	<p><b>Kelly, Patrick 05-10-2019 (00:00:41)</b></p> <p>192:19 THE WITNESS: And included</p> <p>192:20 it in this introduction, yes.</p> <p>192:21 BY MR. PIFKO:</p> <p>192:22 Q. It then says, "Rigorous" --</p> <p>192:23 in the next paragraph, "Rigorous due</p> <p>192:24 diligence can aid in providing a greater</p> <p>193:1 level of assurance that those who</p> <p>193:2 purchase controlled substances from</p> <p>193:3 wholesale distributors intend them to be</p> <p>193:4 used for legitimate and legally</p> <p>193:5 acceptable patient needs."</p> <p>193:6 Did I read that correctly?</p> <p>193:7 A. You did.</p> <p>193:8 Q. "In other words, with such</p> <p>193:9 due diligence, it is possible to reduce</p> <p>193:10 the probability that controlled</p> <p>193:11 substances will reach locations within</p> <p>193:12 the supply chain for which they are not</p> <p>193:13 intended."</p> <p>193:14 Did I read that correctly?</p> <p>193:15 A. You did.</p> <p>193:16 Q. And so HDMA and its members</p> <p>193:17 recognized this to be true at this time</p> <p>193:18 as well, correct?</p>	PK03.58
193:21 - 193:23	<p><b>Kelly, Patrick 05-10-2019 (00:00:02)</b></p> <p>193:21 THE WITNESS: It's what's</p> <p>193:22 stipulated here in this</p>	PK03.59

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215:9 - 215:19	<p>193:23 introduction, yes.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:52)</b></p> <p>215:9 Q. I'm handing you what's</p> <p>215:10 marked as Exhibit 22. It's an e-mail</p> <p>215:11 from HDA's Kristen Freitas dated</p> <p>215:12 Thursday, March 20, 2008. Due to some</p> <p>215:13 sort of way the document was produced,</p> <p>215:14 there's a lot of gibberish and blank</p> <p>215:15 pages, but the substance can be distilled</p> <p>215:16 down to four pages.</p> <p>215:17 But for the record, it's</p> <p>215:18 Bates-labeled ANDA_OPIOIDS_MDL_0000157358</p> <p>215:19 to 157473.</p>	PK03.60
216:5 - 217:8	<p><b>Kelly, Patrick 05-10-2019 (00:00:40)</b></p> <p>216:5 Q. So my first question is, who</p> <p>216:6 is Kristen Freitas?</p> <p>216:7 A. Kristen Freitas is currently</p> <p>216:8 now the vice president of federal</p> <p>216:9 government affairs for HDA, then HDMA.</p> <p>216:10 She was then probably a manager or a</p> <p>216:11 director.</p> <p>216:12 Q. It says here on her</p> <p>216:13 signature on the second page, associate</p> <p>216:14 director.</p> <p>216:15 A. Associate director.</p> <p>216:16 Q. What's federal government</p> <p>216:17 affairs do?</p> <p>216:18 A. Federal government affairs</p> <p>216:19 is tasked primarily with the interface</p> <p>216:20 with Congress. The HDA segment of the</p> <p>216:21 government affairs department that deals</p> <p>216:22 directly with Congress, anything that</p> <p>216:23 happens on the Hill.</p> <p>216:24 Q. Is that a -- something</p> <p>217:1 that's under your purview in your current</p> <p>217:2 position?</p> <p>217:3 A. It is.</p> <p>217:4 Q. Okay. So Kristen Freitas</p> <p>217:5 reports to you?</p> <p>217:6 A. Up through me, yes. I'm the</p>	PK03.61

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217:22 - 218:5	<p>217:7 head of the department. She reports 217:8 directly to our general counsel.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:17)</b></p> <p>217:22 Q. This is a furtherance of the 217:23 overall strategy that we talked about 217:24 that was starting to be implemented in 218:1 Exhibit 3, which derives from the 218:2 executive committee's concerns about 218:3 recent DEA activities to involve 218:4 wholesale distributors in efforts to 218:5 prevent diversion. Do you agree?</p>	PK03.62
218:8 - 218:10	<p><b>Kelly, Patrick 05-10-2019 (00:00:03)</b></p> <p>218:8 THE WITNESS: That should -- 218:9 yes. I would agree it is part of 218:10 that process.</p>	PK03.63
218:12 - 219:7	<p><b>Kelly, Patrick 05-10-2019 (00:00:44)</b></p> <p>218:12 Q. Okay. So then she says 218:13 here, "DEA - as we discussed on the 218:14 federal government affairs committee call 218:15 on Monday, HDMA staff have developed a 218:16 confidential draft political strategy to 218:17 address some of the issues related to DEA 218:18 and suspicious orders. As the document 218:19 states, many of the tactics and messaging 218:20 hinge on the outcome of the DEA meeting 218:21 where we will" -- "we will present our 218:22 recommended industry compliance 218:23 guideline." 218:24 Did I read that correctly?</p> <p>219:1 A. You did.</p> <p>219:2 Q. Okay. So it was understood 219:3 within HDA and its members that, 219:4 depending on this meeting where the 219:5 guidelines were shared with the DEA, that 219:6 would shape how further strategies were 219:7 implemented, agree?</p>	PK03.64
219:10 - 219:11	<p><b>Kelly, Patrick 05-10-2019 (00:00:01)</b></p> <p>219:10 THE WITNESS: I would agree, 219:11 yes.</p>	PK03.65
219:13 - 221:20	<p><b>Kelly, Patrick 05-10-2019 (00:01:59)</b></p>	PK03.66

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219:13 Q. So then we see, if you go to  
219:14 157380, there's a discussion of various  
219:15 tactics that are going to be part of "the  
219:16 HDMA Hill DEA strategy."

219:17 Do you see that?

219:18 A. I do.

219:19 Q. Okay. Tactic Number 1 is,  
219:20 "Complete and present recommended  
219:21 industry compliance guidelines to DEA  
219:22 general counsel."

219:23 Do you see that?

219:24 A. Yes.

220:1 Q. Okay. You agree that's the  
220:2 first tactic mentioned here?

220:3 A. That is, yes.

220:4 Q. And then it says, "Status:  
220:5 Request to be made the week of  
220:6 March 17th."

220:7 Agree?

220:8 A. That's what it says, yes.

220:9 Q. And like we just saw in the  
220:10 prior department, "The discussion and  
220:11 outcome of this meeting will be critical  
220:12 in driving all further tactics and  
220:13 messaging."

220:14 Agree?

220:15 A. That's what it says, yes.

220:16 Q. Then it says, "Brief House  
220:17 appropriation subcommittee members who  
220:18 participated in the March 12th DEA budget  
220:19 justification hearing. Seek questions to  
220:20 be asked for the record."

220:21 Do you see that?

220:22 A. Yes.

220:23 Q. Do you have an understanding  
220:24 about what that was about?

221:1 A. Again, I think it had to do  
221:2 with, and the timing of this would have  
221:3 been -- if this is after the -- the  
221:4 hearing. This was on March 20th.

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221:5 Again, I think it was  
 221:6 basically when FDA or DEA on an annual  
 221:7 basis goes before the appropriation  
 221:8 committee to discuss their budget, that  
 221:9 if there were concerns or questions about  
 221:10 their perspective on our guidelines or  
 221:11 their suspicious order monitoring  
 221:12 tactics, that we provide some feedback to  
 221:13 the appropriation members so they could  
 221:14 ask for further clarification from the  
 221:15 administrator while she was there  
 221:16 testifying.

221:17 Q. Okay. And so you drafted,  
 221:18 on behalf of your members, potential  
 221:19 questions to be asked by members of  
 221:20 Congress to ask the DEA, correct?

221:23 - 221:24

**Kelly, Patrick 05-10-2019 (00:00:01)**

PK03.67

221:23 THE WITNESS: That's what I  
 221:24 understand these to be, yes.

222:5 - 223:4

**Kelly, Patrick 05-10-2019 (00:00:43)**

PK03.68

222:5 Q. Tactic 3 is, "Brief  
 222:6 Senate appropriation subcommittee members  
 222:7 in advance of DEA budget justification  
 222:8 hearing. Seek commitment to ask  
 222:9 questions of DEA administrator."  
 222:10 Do you see that?  
 222:11 A. Yes.  
 222:12 Q. Do you have an understanding  
 222:13 what that's about?  
 222:14 A. Again, similar to what was  
 222:15 done on the House side. But again maybe  
 222:16 those questions were developed for the  
 222:17 Senate side, because it appears that this  
 222:18 e-mail was sent after the 3/12  
 222:19 appropriations committee.  
 222:20 Q. Okay. So these questions  
 222:21 are for senators to ask the DEA?  
 222:22 A. I would deduce that  
 222:23 that's -- yes, that's the process.  
 222:24 Q. And that's a common tactic

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223:1 that you use in the organization, is to 223:2 draft questions for senators or members 223:3 of Congress to ask DEA if you have 223:4 concerns?		
223:7 - 223:19	<b>Kelly, Patrick 05-10-2019 (00:00:18)</b> 223:7 THE WITNESS: That is a 223:8 common practice for a lot of 223:9 associations that interact with 223:10 regulatory authorities. 223:11 BY MR. PIFKO: 223:12 Q. Including HDA? 223:13 A. In this instance including 223:14 HDA. 223:15 Q. And so when it says, "Brief 223:16 senate appropriation subcommittees in 223:17 advance of the hearing," there's also 223:18 one-on-one meetings that occur with the 223:19 senators in advance of the hearing?	PK03.69
223:22 - 224:7	<b>Kelly, Patrick 05-10-2019 (00:00:12)</b> 223:22 THE WITNESS: I would 223:23 imagine these are primarily 223:24 meetings with staff, 224:1 staff-to-staff meetings. Seldom 224:2 to the member representatives 224:3 participate in those meetings. So 224:4 these are staff briefings. 224:5 BY MR. PIFKO: 224:6 Q. That's where the questions 224:7 are provided?	PK03.70
224:10 - 225:3	<b>Kelly, Patrick 05-10-2019 (00:00:27)</b> 224:10 THE WITNESS: Again, that's 224:11 where I -- if they were provided, 224:12 again, I don't know what was 224:13 provided. This was looking at a 224:14 draft document of some kind. I am 224:15 not sure which specific questions 224:16 were provided or if any of the 224:17 questions were provided. 224:18 BY MR. PIFKO: 224:19 Q. Okay. But in your ordinary	PK03.71

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
	224:20 practice as part of your lobbying 224:21 efforts, that's how questions would be 224:22 provided, you would have your staff 224:23 members meet with lawmakers' staff 224:24 members and that's when you would discuss 225:1 your views and provide potential 225:2 questions? 225:3 A. Correct.	
225:8 - 225:19	<b>Kelly, Patrick 05-10-2019 (00:00:25)</b> 225:8 Q. Go a few more tactics down. 225:9 Number 6, it says, "Educate and seek 225:10 advocates for HDMA among pain community 225:11 who will assist in delivering our message 225:12 to Hill." 225:13 Do you see that? 225:14 A. I do. 225:15 Q. So you were going to, as 225:16 part of this effort, you were going to 225:17 also enlist others in the pain community 225:18 to communicate your message to lawmakers; 225:19 that's correct?	PK03.72
225:22 - 225:23	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b> 225:22 THE WITNESS: That's what 225:23 this indicates.	PK03.73
226:1 - 226:16	<b>Kelly, Patrick 05-10-2019 (00:00:28)</b> 226:1 Q. And then it says, "Status, 226:2 HDMA joined and briefed the Pain Care 226:3 Forum, an informal coalition of 226:4 pharmaceutical companies and patient 226:5 advocacy groups focusing on pain 226:6 management issues and will follow up upon 226:7 release of our industry compliance 226:8 guidelines." 226:9 Did I read that correctly? 226:10 A. You did. 226:11 Q. Okay. And so that confirms 226:12 HDMA did join the Pain Care Forum, 226:13 correct? 226:14 A. Yes. In 2008. 226:15 Q. And you briefed them on	PK03.74

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
226:19 - 227:3	<p>226:16 these issues, correct?</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:11)</b></p> <p>226:19 THE WITNESS: Again, this</p> <p>226:20 seems to indicate that we briefed</p> <p>226:21 them that we were developing the</p> <p>226:22 industry compliance guidelines</p> <p>226:23 just to give them a heads-up. And</p> <p>226:24 we were indicating to this, we</p> <p>227:1 would share our final document</p> <p>227:2 when it was developed and</p> <p>227:3 released.</p>	PK03.75
227:24 - 228:19	<p><b>Kelly, Patrick 05-10-2019 (00:00:36)</b></p> <p>227:24 Q. And then Number 8 says,</p> <p>228:1 "Identify high-level congressional</p> <p>228:2 'champion' who will request a meeting</p> <p>228:3 with DEA to discuss concerns with current</p> <p>228:4 tactics."</p> <p>228:5 Do you see that?</p> <p>228:6 A. I do.</p> <p>228:7 Q. Do you have an understanding</p> <p>228:8 about what that's about?</p> <p>228:9 A. Again, what it says. So</p> <p>228:10 probably ask a member of Congress,</p> <p>228:11 possibly a high-level senior ranking</p> <p>228:12 official or a ranking member in their</p> <p>228:13 party to request a meeting with DEA,</p> <p>228:14 possibly a committee chairman of some</p> <p>228:15 kind, a relevant committee.</p> <p>228:16 Q. And so at this time HDMA and</p> <p>228:17 its members were concerned with the</p> <p>228:18 enforcement tactics being used by the</p> <p>228:19 DEA, correct?</p>	PK03.76
228:22 - 229:10	<p><b>Kelly, Patrick 05-10-2019 (00:00:22)</b></p> <p>228:22 THE WITNESS: I think -- I</p> <p>228:23 think there was concern about the</p> <p>228:24 lack of clarity and basically what</p> <p>229:1 we were trying to basically convey</p> <p>229:2 in some of the questions that were</p> <p>229:3 put together. So we were -- yeah,</p> <p>229:4 we were seeking greater clarity</p>	PK03.77

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
229:5 from the agency and it was not 229:6 forthcoming, and so we were 229:7 requesting that our congressional 229:8 colleagues possibly request a 229:9 meeting so we could convey those 229:10 concerns.		
229:11 - 229:14	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 229:11 BY MR. PIFKO: 229:12 Q. When I handed you this 229:13 document, you read it in its entirety, 229:14 correct?	PK03.181
229:21 - 231:1	<b>Kelly, Patrick 05-10-2019 (00:01:05)</b> 229:21 Q. You read the questions -- 229:22 potential Hill questions for DEA, right? 229:23 A. I did, yes. 229:24 Q. Okay. And so the thrust of 230:1 the questions, you know, goes at the end 230:2 here. It says, if you look on 157382, 230:3 "Isn't your initiative overly broad and 230:4 not focused specifically enough on rogue 230:5 pharmacies, which in fact make up a 230:6 miniscule percentage of any legitimate 230:7 wholesaler's business?" 230:8 And then it says, "Clearly, 230:9 if a customer is known to be diverting 230:10 prescription drugs and the wholesale 230:11 distributor continues to supply that 230:12 customer, a violation of their registrant 230:13 responsibilities as has occurred. But my 230:14 concern here is that your expectations go 230:15 to a much higher level, asking the 230:16 wholesaler in essence to be your 230:17 investigator. I don't think that's 230:18 appropriate. It seems to me at the end 230:19 of the day that prescription drug abuse 230:20 is caused by inappropriate prescribing 230:21 and inappropriate dispensing, neither of 230:22 which wholesalers are authorized or 230:23 capable of regulating or enforcing." 230:24 Do you see that?	PK03.78

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
231:8 - 231:12	<p>231:1 A. I do.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:06)</b></p> <p>231:8 Q. But at this stage it's a</p> <p>231:9 potential question for some lawmaker to</p> <p>231:10 ask the DEA, correct?</p> <p>231:11 A. That's -- yes. That's the</p> <p>231:12 context for this.</p>	PK03.79
231:17 - 231:19	<p><b>Kelly, Patrick 05-10-2019 (00:00:12)</b></p> <p>231:17 Q. I'm handing you what's</p> <p>231:18 marked Exhibit 23. If you recall,</p> <p>231:19 earlier on in Exhibit 8, there was an</p>	PK03.80
231:20 - 232:5	<p><b>Kelly, Patrick 05-10-2019 (00:00:24)</b></p> <p>231:20 e-mail from Anita Ducca that attached</p> <p>231:21 some of her draft summaries of the</p> <p>231:22 various meetings and events that occurred</p> <p>231:23 in connection with the industry</p> <p>231:24 compliance guidelines and meetings with</p> <p>232:1 the DEA. And this is -- Exhibit 23, is</p> <p>232:2 one of those attachments. She said, if</p> <p>232:3 you recall, these were draft summaries of</p> <p>232:4 her meetings.</p> <p>232:5 A. Yes.</p>	PK03.194
232:13 - 232:17	<p><b>Kelly, Patrick 05-10-2019 (00:00:08)</b></p> <p>232:13 Q. So this is a summary of the</p> <p>232:14 first meeting that HDA had with DEA</p> <p>232:15 concerning the industry compliance</p> <p>232:16 guidelines, correct?</p> <p>232:17 A. That's correct.</p>	PK03.81
232:21 - 233:9	<p><b>Kelly, Patrick 05-10-2019 (00:00:25)</b></p> <p>232:21 Q. And in addition to HDMA</p> <p>232:22 members, it also identifies Richard</p> <p>232:23 Cooper from Williams &amp; Connolly as an</p> <p>232:24 attendee and David Durkin from Olsson</p> <p>233:1 Frank law firm as well?</p> <p>233:2 A. It does, yes.</p> <p>233:3 Q. And who is Robert Barnett,</p> <p>233:4 is he -- is he from Williams &amp; Connolly</p> <p>233:5 as well?</p> <p>233:6 A. Yes.</p> <p>233:7 Q. Okay. They were outside</p>	PK03.82

Page/Line	Source	ID
233:8	counsel to HDA at this time?	
233:9	A. Yes.	
233:16 - 234:12	<b>Kelly, Patrick 05-10-2019 (00:00:48)</b>	PK03.83
233:16	Q. So Ms. Ducca has a meeting	
233:17	summary here. So it appears that Bob	
233:18	Barnett and Rich Cooper led the	
233:19	introductory remarks in the meeting,	
233:20	agree?	
233:21	A. Yes. They led off.	
233:22	Q. Okay. So, Bob explained the	
233:23	purpose of the meeting. He explained --	
233:24	I'm reading from the document -- "the	
234:1	serious concerns among HDMA members	
234:2	regarding DEA's recent actions regarding	
234:3	suspicious orders. When HDMA first	
234:4	contacted Williams & Connolly regarding	
234:5	possibly challenging DEA, Bob and Rich	
234:6	Cooper recommended an alternative that	
234:7	was based on his prior experience with	
234:8	other clients in similar positions."	
234:9	Do you see that?	
234:10	A. I do.	
234:11	Q. Did I read that correctly?	
234:12	A. You did.	
234:23 - 235:13	<b>Kelly, Patrick 05-10-2019 (00:00:30)</b>	PK03.84
234:23	Q. And so Williams & Connolly	
234:24	recommended that, instead of challenging	
235:1	the DEA, that the distributors develop a	
235:2	set of business practices of their own	
235:3	or, as this says, "a type of standard as	
235:4	a better approach to show DEA to the	
235:5	outside world what is intended" -- "that	
235:6	they intend to be part of the solution	
235:7	rather than problem"; is that correct?	
235:8	A. That's correct. Those were	
235:9	his words, yes.	
235:10	Q. And that's what he told DEA	
235:11	at this meeting?	
235:12	A. I will take it at face value	
235:13	that that's what was explained, yes.	

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
235:14 - 235:21	<b>Kelly, Patrick 05-10-2019 (00:00:18)</b> 235:14 Q. Other points that Bob 235:15 Barnett made were that "HDMA hoped that 235:16 DEA would find the guidelines acceptable 235:17 as a voluntary 'consent decree,' and we 235:18 hoped to receive some form of imprimatur 235:19 from you." 235:20 Agree? 235:21 A. That's what it says, yes.	PK03.85
235:22 - 236:6	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b> 235:22 Q. It's noted here, Bob also 235:23 told DEA, "These guidelines have been 235:24 adopted and approved by HDMA's board." 236:1 Agree? 236:2 A. Which bullet point are you 236:3 on? 236:4 Q. Second to last on the first 236:5 page. 236:6 A. Yes.	PK03.195
236:7 - 236:10	<b>Kelly, Patrick 05-10-2019 (00:00:08)</b> 236:7 Q. But then it was explained 236:8 that HDMA and its board were open to 236:9 suggestions from the DEA, correct? 236:10 A. That's correct.	PK03.169
236:17 - 237:7	<b>Kelly, Patrick 05-10-2019 (00:00:34)</b> 236:17 Q. So -- then, we're going to 236:18 the second page here. So it says, "After 236:19 Bob's introductory discussion, he turned 236:20 the meeting over to Richard Cooper from 236:21 Williams & Connolly." 236:22 Agree? 236:23 A. Yes. 236:24 Q. Okay. And so Rich is the 237:1 one who had this previous experience with 237:2 the FDA where they developed standards 237:3 that were voluntary and eventually became 237:4 standard practice among the medical 237:5 research community, and this idea of the 237:6 industry compliance guidelines was born 237:7 out of that, agree?	PK03.87

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
237:10 - 237:15	<b>Kelly, Patrick 05-10-2019 (00:00:05)</b> 237:10 THE WITNESS: I think that's 237:11 what's being implied here, yes. 237:12 BY MR. PIFKO: 237:13 Q. And that's what was told to 237:14 DEA in connection with this meeting, 237:15 correct?	PK03.183
237:18 - 237:20	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 237:18 THE WITNESS: That's -- 237:19 again, that's what it -- seems to 237:20 be stipulated here, yes.	PK03.182
237:22 - 239:6	<b>Kelly, Patrick 05-10-2019 (00:00:56)</b> 237:22 Q. So a key point, according to 237:23 Anita's notes is that Rich Cooper from 237:24 Williams & Connolly made, was that "an 238:1 order and question will be stopped until 238:2 there was an assessment and found that 238:3 the order was not suspicious." 238:4 Agree? 238:5 A. Where -- 238:6 Q. Second paragraph, full 238:7 paragraph of Page 2. 238:8 A. Okay. Yes. I see that, 238:9 yes. 238:10 Q. And so then, DEA had a 238:11 question about "what exactly are you 238:12 stopping when you stop the order?" 238:13 A. Okay. 238:14 Q. And that's some discussion 238:15 about that. 238:16 Do you see that? 238:17 A. Yes. 238:18 Q. And so then, Rich Cooper 238:19 told DEA that "the guidelines indicated 238:20 that the entire order of the specific 238:21 product that triggered the threshold 238:22 should be held and not released." 238:23 Do you see that? 238:24 A. Yes. 239:1 Q. And then he also said, "The	PK03.89

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
239:2	guidelines expected that the entire order	
239:3	for the drug product in question would be	
239:4	held, even if part of it came under a	
239:5	threshold."	
239:6	Do you see that?	
239:9 - 239:10	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b>	PK03.196
239:9	THE WITNESS: Yes. Last	
239:10	sentence.	
240:8 - 240:11	<b>Kelly, Patrick 05-10-2019 (00:00:06)</b>	PK03.92
240:8	Q. So then the meeting was	
240:9	handed over to Scott Melville, your --	
240:10	your predecessor, agree?	
240:11	A. Yes.	
241:5 - 241:12	<b>Kelly, Patrick 05-10-2019 (00:00:19)</b>	PK03.93
241:5	Q. And Scott also told DEA that	
241:6	"HDA would discuss, explain and encourage	
241:7	acceptance of the guidelines by other	
241:8	trade associations, including	
241:9	manufacturing and pharmacy groups."	
241:10	That's the second bullet	
241:11	point on the page?	
241:12	A. Yes, yes, yes, yes, yes.	
241:13 - 241:19	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b>	PK03.189
241:13	Q. So you agree, a key message	
241:14	that Scott was communicating to DEA here	
241:15	was that HDA was going to work to make	
241:16	sure its members and other participants	
241:17	in the supply chain in the pharmaceutical	
241:18	industry would implement these	
241:19	guidelines, correct?	
241:22 - 242:8	<b>Kelly, Patrick 05-10-2019 (00:00:18)</b>	PK03.185
241:22	THE WITNESS: I think we --	
241:23	we meant to basically educate the	
241:24	rest, that they were available.	
242:1	Again, we are not a	
242:2	standards agency, we are not a	
242:3	regulatory authority. We can't	
242:4	basically make any entity comply	
242:5	with the guidelines. We were just	
242:6	going to educate as many folks as	

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
242:10 - 242:12	<p>242:7 we could about their existence and</p> <p>242:8 make them available.</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:04)</b></p> <p>242:10 Q. But you told DEA that you</p> <p>242:11 wanted to help your members implement the</p> <p>242:12 guidelines, correct?</p>	PK03.95
242:15 - 242:17	<p><b>Kelly, Patrick 05-10-2019 (00:00:02)</b></p> <p>242:15 THE WITNESS: That's -- yes,</p> <p>242:16 that's what it -- that's what it</p> <p>242:17 says here, yes.</p>	PK03.96
248:9 - 248:11	<p><b>Kelly, Patrick 05-10-2019 (00:00:06)</b></p> <p>248:9 Q. To your knowledge, did any</p> <p>248:10 distributor implement the industry</p> <p>248:11 compliance guidelines?</p>	PK03.97
248:14 - 249:10	<p><b>Kelly, Patrick 05-10-2019 (00:00:33)</b></p> <p>248:14 THE WITNESS: Again, I don't</p> <p>248:15 know. They were -- they were</p> <p>248:16 guidelines. Many of the</p> <p>248:17 companies, from what I understand,</p> <p>248:18 already had various processes in</p> <p>248:19 place. These guidelines were</p> <p>248:20 developed to better inform them</p> <p>248:21 about expectations within the DEA.</p> <p>248:22 And if they -- they could beg and</p> <p>248:23 borrow, and again it was meant to</p> <p>248:24 be kind of something that could be</p> <p>249:1 applicable to various size</p> <p>249:2 companies and be able to adapt.</p> <p>249:3 So again I don't know if</p> <p>249:4 anybody adopted the entire</p> <p>249:5 document verbatim or not. And we</p> <p>249:6 didn't ask.</p> <p>249:7 BY MR. PIFKO:</p> <p>249:8 Q. You don't know if anybody</p> <p>249:9 adopted parts of the document either,</p> <p>249:10 correct?</p>	PK03.98
249:13 - 249:13	<p><b>Kelly, Patrick 05-10-2019 (00:00:00)</b></p> <p>249:13 THE WITNESS: We don't.</p>	PK03.99
249:15 - 249:19	<p><b>Kelly, Patrick 05-10-2019 (00:00:10)</b></p> <p>249:15 Q. So sitting here today, you</p>	PK03.100

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
249:22 - 249:23	<p>249:16 don't know, and at no time does HDMA know</p> <p>249:17 if any members or other distributors</p> <p>249:18 adopted all or part of the industry</p> <p>249:19 compliance guidelines, correct?</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:01)</b></p> <p>249:22 THE WITNESS: I don't know,</p> <p>249:23 nor did we ask.</p>	PK03.101
249:24 - 250:5	<p><b>Kelly, Patrick 05-10-2019 (00:00:08)</b></p> <p>249:24 stated before, we are not a</p> <p>250:1 regulatory authority; we are not a</p> <p>250:2 standard-setting body. We are</p> <p>250:3 simply doing our best to inform</p> <p>250:4 our members about existing</p> <p>250:5 policies.</p>	PK03.170
251:7 - 251:13	<p><b>Kelly, Patrick 05-10-2019 (00:00:15)</b></p> <p>251:7 Q. Okay. And just to be</p> <p>251:8 clear -- I think you had the answer, but</p> <p>251:9 I don't think we have a clear record.</p> <p>251:10 To your knowledge, no</p> <p>251:11 distributor, manufacturer, or pharmacy</p> <p>251:12 has ever implemented the guidelines or</p> <p>251:13 any portion of the guidelines, correct?</p>	PK03.102
251:16 - 252:3	<p><b>Kelly, Patrick 05-10-2019 (00:00:19)</b></p> <p>251:16 THE WITNESS: Again, I think</p> <p>251:17 every distributor member has their</p> <p>251:18 own compliance guidelines that are</p> <p>251:19 basically developed and put in</p> <p>251:20 place for their company, their</p> <p>251:21 specific customer base, et cetera.</p> <p>251:22 I don't know that anybody kind of</p> <p>251:23 copied the industry compliance</p> <p>251:24 guidelines and made it part of</p> <p>252:1 their own protocols and</p> <p>252:2 procedures. I don't know. Nor</p> <p>252:3 did we ask.</p>	PK03.103
263:20 - 264:3	<p><b>Kelly, Patrick 05-10-2019 (00:00:37)</b></p> <p>263:20 Q. I'm handing you what's</p> <p>263:21 marked as Exhibit 26. These are</p> <p>263:22 Ms. Ducca's notes from the second meeting</p> <p>263:23 with DEA on suspicious orders which was</p>	PK03.104

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
	263:24 attached to Exhibit 8, I believe.	
	264:1 For the record, it's	
	264:2 Bates-labeled CAH_MDL2804_02489191	
	264:3 through 196.	
264:9 - 264:23	<b>Kelly, Patrick 05-10-2019 (00:00:32)</b>	PK03.105
	264:9 Q. So these are Ms. Ducca's	
	264:10 notes of the second meeting with DEA,	
	264:11 correct?	
	264:12 A. Yes.	
	264:13 Q. And if you recall, from the	
	264:14 notes from the first meeting, one of the	
	264:15 comments was that they welcomed DEA's	
	264:16 input on the draft that had been shared	
	264:17 at the prior meeting, agree?	
	264:18 A. Yes.	
	264:19 Q. And so then, this is DEA	
	264:20 providing its comments on the industry	
	264:21 compliance guidelines that had been	
	264:22 provided to them at the prior meeting,	
	264:23 agree?	
265:2 - 265:2	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b>	PK03.106
	265:2 THE WITNESS: Yes.	
265:4 - 266:9	<b>Kelly, Patrick 05-10-2019 (00:01:18)</b>	PK03.107
	265:4 Q. And it's got the attendees	
	265:5 here from DEA, it includes Linden Barber,	
	265:6 Cathy Gallagher, Robert Gleason, agree?	
	265:7 A. Yes.	
	265:8 Q. And then from HDMA, we've	
	265:9 got Ms. Ducca, Scott Melville. And	
	265:10 you've got outside counsel, Robert	
	265:11 Burnett, Richard Cooper, and David	
	265:12 Durkin, agree?	
	265:13 A. Yes.	
	265:14 Q. Okay. So they just go	
	265:15 through the draft guidelines that were	
	265:16 provided to them, which are the ones that	
	265:17 were in Exhibit 21.	
	265:18 So then, it goes through	
	265:19 page by page providing thoughts and	
	265:20 comments DEA has, agree?	

Page/Line	Source	ID
	265:21 A. Yes, that's what these notes	
	265:22 do.	
	265:23 Q. That's what's reflected in	
	265:24 Exhibit 26, correct?	
	266:1 A. Yes.	
	266:2 Q. Okay. So one comment DEA	
	266:3 has is that, "It's recommended that you	
	266:4 add into the outline that once an order	
	266:5 is determined to be suspicious, it	
	266:6 shouldn't be shipped. DEA understood	
	266:7 that it was in the body of the	
	266:8 guidelines, but they wanted to see it	
	266:9 upfront in the outline as well." Agreed?	
266:15 - 267:11	<b>Kelly, Patrick 05-10-2019 (00:00:54)</b>	PK03.108
	266:15 Q. Page 3.	
	266:16 A. Page 3, I'm sorry.	
	266:17 Q. No I'm on the first page of	
	266:18 Exhibit 26. But I'm looking at the	
	266:19 comment from Page 3.	
	266:20 A. Oh, I'm sorry. Okay, yes.	
	266:21 Q. DEA is just emphasizing that	
	266:22 the -- if an order is suspicious, it	
	266:23 shouldn't be shipped. They want that up	
	266:24 in the front in the outline, even though	
	267:1 it's in the body of the document, agreed?	
	267:2 A. That's what this notes says,	
	267:3 yes.	
	267:4 Q. The comment for Page 4, Item	
	267:5 1B is saying that for a questionnaire	
	267:6 that might be to a distributor's	
	267:7 customer, DEA wants the industry to be	
	267:8 aware that even if you obtain a signed	
	267:9 document, that's not going to be a	
	267:10 defense; distributors have to do more to	
	267:11 identify the legitimacy, agree?	
267:14 - 267:17	<b>Kelly, Patrick 05-10-2019 (00:00:11)</b>	PK03.109
	267:14 THE WITNESS: Yes, that's	
	267:15 what it says.	
	267:16 BY MR. PIFKO:	
	267:17 Q. Turning to the second page.	

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
267:22 - 268:2	<b>Kelly, Patrick 05-10-2019 (00:00:13)</b> 267:22 It says, 267:23 "Several times they" -- which is DEA, 267:24 "they said that the procedures" -- 268:1 "procedures used by members should be 268:2 robust and adaptable," agree?	PK03.110
268:5 - 268:6	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b> 268:5 THE WITNESS: That's what it 268:6 says.	PK03.111
268:8 - 270:13	<b>Kelly, Patrick 05-10-2019 (00:01:42)</b> 268:8 Q. Okay. And then the longer 268:9 comment here for Section 2, monitoring on 268:10 suspicious orders, the second paragraph 268:11 here, it says, "DEA seemed to think that 268:12 thresholds focus primarily on volumes and 268:13 they expressed the view that an exclusive 268:14 or even principal focus on volumes is 268:15 inadequate." 268:16 Do you see that? 268:17 A. I do. 268:18 Q. Do you agree that that's 268:19 what DEA told HDMA during this meeting? 268:20 A. I have no reason to doubt 268:21 what's written here. 268:22 Q. Okay. And that's what's 268:23 written here, correct? 268:24 A. That's what's written here. 269:1 Q. "They also want the initial 269:2 screen of orders to focus on A, patterns 269:3 of ordering, comparing the present order 269:4 to, one, past orders from the same 269:5 customer including whether the frequency 269:6 of orders is suspicious; two, orders from 269:7 similar customers; and, three, orders 269:8 from other establishments of the same 269:9 type in the locale or region." Agree? 269:10 A. That's what it says. 269:11 Q. Okay. And then they also 269:12 want the initial screens of orders to 269:13 focus on combination of controlled	PK03.112

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	269:14 substances ordered, agree?	
	269:15 A. That's what it says, yes.	
	269:16 Q. Then going to the third	
	269:17 page, at the top, another comment that	
	269:18 DEA made here, it says, was that the term	
	269:19 "order of interest" did not have legal	
	269:20 standing.	
	269:21 Do you see that?	
	269:22 A. I do.	
	269:23 Q. Okay. And that was	
	269:24 something that DEA conveyed at this	
	270:1 meeting, correct?	
	270:2 A. Again, I'll take it from	
	270:3 this, yes, that they did that.	
	270:4 Q. And then it says, "DEA	
	270:5 emphasized that orders should not remain	
	270:6 in the orders of interest category for	
	270:7 lengthy periods."	
	270:8 Do you see that?	
	270:9 A. Yes.	
	270:10 Q. "They should be investigated	
	270:11 expeditiously and promptly resolved as	
	270:12 either suspicious or not suspicious."	
	270:13 Agree?	
270:16 - 270:17	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b>	PK03.113
	270:16 THE WITNESS: That's what it	
	270:17 says, yes.	
270:19 - 270:24	<b>Kelly, Patrick 05-10-2019 (00:00:09)</b>	PK03.171
	270:19 Q. Okay. Then there's some	
	270:20 comments about the language about	
	270:21 thresholds that was in the draft industry	
	270:22 compliance guidelines.	
	270:23 Do you see that section?	
	270:24 A. I do.	
270:19 - 272:19	<b>Kelly, Patrick 05-10-2019 (00:01:28)</b>	PK03.114
	270:19 Q. Okay. Then there's some	
	270:20 comments about the language about	
	270:21 thresholds that was in the draft industry	
	270:22 compliance guidelines.	
	270:23 Do you see that section?	

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270:24 A. I do.

271:1 Q. Okay. So the first is that,

271:2 "DEA thought it might be interpreted to

271:3 mean excessive volumes only. And then

271:4 HDMA responded that their intent was to

271:5 be broader and to include frequency as a

271:6 factor."

271:7 Do you see that?

271:8 A. I do.

271:9 Q. Okay. "DEA asked HDA to

271:10 expand the explanation of thresholds,"

271:11 agreed?

271:12 A. That's what it says, yes.

271:13 Q. And then, "DEA asked that

271:14 the industry compliance guidelines say

271:15 the drug or drugs that cause an order to

271:16 be an order of interest should not be

271:17 shipped where the order is an order of

271:18 interest."

271:19 Do you see that?

271:20 A. I do.

271:21 Q. Okay. You agree that that

271:22 was something that the DEA conveyed at

271:23 this meeting?

271:24 A. Again, I have no reason to

272:1 doubt what was stated here on this paper.

272:2 Q. And then finally, it says,

272:3 "DEA suggested that we delete the second

272:4 paragraph under C, develop thresholds to

272:5 identify orders of interest."

272:6 Do you see that?

272:7 A. I do.

272:8 Q. It says, "DEA has backed

272:9 away from the standard of three times the

272:10 monthly overage order for Schedule II and

272:11 ARCOS-reportable Schedule III products.

272:12 DEA suggested that we substitute a

272:13 paragraph based on more recent DEA

272:14 guidance."

272:15 Do you see that?

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	272:16 A. I do.	
	272:17 Q. So you understood that DEA	
	272:18 was communicating here not to use the	
	272:19 three times multiplier, correct?	
272:22 - 272:23	<b>Kelly, Patrick 05-10-2019 (00:00:02)</b>	PK03.115
	272:22 THE WITNESS: That seems to	
	272:23 be what this indicates, yes.	
274:1 - 274:15	<b>Kelly, Patrick 05-10-2019 (00:00:23)</b>	PK03.116
	274:1 Q. Okay. And then we go to the	
	274:2 section on Page 8 in the guidelines,	
	274:3 "Stop shipments of an order of interest."	
	274:4 Do you see that?	
	274:5 A. I do.	
	274:6 Q. And then it says, "DEA asked	
	274:7 us to reemphasize that an order should	
	274:8 not be shipped" -- and it's underlined --	
	274:9 "if there was reason to believe there was	
	274:10 a problem."	
	274:11 Do you see that?	
	274:12 A. I do.	
	274:13 Q. So DEA made that point	
	274:14 again, correct?	
	274:15 A. Yes.	
277:12 - 277:24	<b>Kelly, Patrick 05-10-2019 (00:00:27)</b>	PK03.117
	277:12 Q. I want to go to the last	
	277:13 page of this document. The comment from	
	277:14 Page 11, "DEA asked us to emphasize that	
	277:15 suspicious order must be reported to DEA	
	277:16 whether the wholesaler ships or not, and	
	277:17 to emphasize that timeliness of notice is	
	277:18 very important."	
	277:19 Do you see that?	
	277:20 A. I do.	
	277:21 Q. Do you agree that that was	
	277:22 something communicated during this	
	277:23 meeting?	
	277:24 A. I do.	
279:2 - 279:12	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b>	PK03.118
	279:2 Q. And then there's additional	
	279:3 comments that DEA raised that are	

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279:4 provided in bullet points here at the  
 279:5 end. Agree?  
 279:6 A. I see them.  
 279:7 Q. Five of them?  
 279:8 A. Yes.  
 279:9 Q. One is yet another comment  
 279:10 that if an order is -- there's concerns  
 279:11 or questions, it shouldn't be shipped,  
 279:12 agree?

279:15 - 281:3

**Kelly, Patrick 05-10-2019 (00:01:00)**

PK03.119

279:15 THE WITNESS: The first  
 279:16 bullet point?  
 279:17 BY MR. PIFKO:  
 279:18 Q. Yeah. That's what it says?  
 279:19 A. That's what it says.  
 279:20 Q. They want reports on all  
 279:21 orders, even if it's not shipped?  
 279:22 A. On all suspicious orders.  
 279:23 Yes. Bullet Point 2.  
 279:24 Q. Again, a comment about  
 280:1 timeliness in Bullet 3, agree?  
 280:2 A. Yes.  
 280:3 Q. And then 4, it says, "DEA  
 280:4 wants reports of suspicious orders even  
 280:5 if there is some question about the  
 280:6 dispenser status as a customer. For  
 280:7 example, if during a background check of  
 280:8 a potential customer, the customer  
 280:9 indicates that they might be placing  
 280:10 orders that could be suspicious, DEA  
 280:11 wants to know, even if the pharmacy in  
 280:12 question does not become a customer."  
 280:13 Agree, that's what it says?  
 280:14 A. That's what it says, yes.  
 280:15 Q. So you understood that DEA  
 280:16 communicated that as well during this  
 280:17 meeting?  
 280:18 A. Again, I have no reason to  
 280:19 doubt what's written here.  
 280:20 Q. Okay. We know these

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	280:21 comments were shared with Cardinal, 280:22 because we have the e-mail. 280:23 To your knowledge, in the 280:24 ordinary course of HDA's processes and 281:1 procedures, these would -- these would 281:2 have been shared with other members as 281:3 well, correct?	
281:8 - 281:13	<b>Kelly, Patrick 05-10-2019 (00:00:09)</b> 281:8 THE WITNESS: Again, I can't 281:9 say for certain. This is labeled 281:10 as a draft. I'm not sure if it 281:11 was sent to the RAC or another 281:12 group, until -- again, all I have 281:13 is the form in front of me so...	PK03.172
281:14 - 281:19	<b>Kelly, Patrick 05-10-2019 (00:00:06)</b> 281:14 I would -- I would imagine 281:15 so, that usually we sent -- we're 281:16 usually in the habit of 281:17 summarizing those meetings and 281:18 sending them out to the regulatory 281:19 affairs committee.	PK03.120
282:17 - 282:19	<b>Kelly, Patrick 05-10-2019 (00:00:07)</b> 282:17 Q. Okay. So HDA certainly 282:18 would have shared the views of DEA to its 282:19 members after this meeting, agree?	PK03.121
282:22 - 282:24	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 282:22 THE WITNESS: Again, I don't 282:23 doubt that they did. I just -- 282:24 I'm looking at a draft document.	PK03.173
283:1 - 283:5	<b>Kelly, Patrick 05-10-2019 (00:00:08)</b> 283:1 So again, I don't doubt that 283:2 this was finalized and the edits 283:3 made here were incorporated and a 283:4 final document was submitted to 283:5 the regulatory affairs committee.	PK03.122
284:1 - 284:2	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 284:1 Q. I'm handing you what's 284:2 marked as Exhibit 27.	PK03.123
284:8 - 284:9	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 284:8 this is the	PK03.124

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
284:12 - 284:14	<p>284:9 final guidelines, correct?</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:14)</b></p> <p>284:12 For the record, Exhibit 27</p> <p>284:13 is a document Bates-labeled</p> <p>284:14 HDA_MDL_00218651 through 218665.</p>	PK03.125
284:15 - 284:17	<p><b>Kelly, Patrick 05-10-2019 (00:00:04)</b></p> <p>284:15 A. Yes, I would agree that this</p> <p>284:16 is the final version of the industry</p> <p>284:17 compliance guidelines.</p>	PK03.186
287:15 - 287:23	<p><b>Kelly, Patrick 05-10-2019 (00:00:38)</b></p> <p>287:15 Q. Handing you what's been</p> <p>287:16 marked as Exhibit 29. For the record,</p> <p>287:17 Exhibit 29 is a webinar slide</p> <p>287:18 presentation dated Friday, November 14th,</p> <p>287:19 2008. The title "Industry Compliance</p> <p>287:20 Guidelines. Reporting Suspicious Orders</p> <p>287:21 and Preventing Diversion of Controlled</p> <p>287:22 Substances." It's Bates-labeled</p> <p>287:23 HDA_MDL_000145918 through 145968.</p>	PK03.126
288:4 - 288:15	<p><b>Kelly, Patrick 05-10-2019 (00:00:21)</b></p> <p>288:4 Q. So you recall in the first</p> <p>288:5 meeting with DEA about the industry</p> <p>288:6 compliance guidelines on April 15, 2008,</p> <p>288:7 one of the thing HDA told DEA that it was</p> <p>288:8 going to engage in an educational</p> <p>288:9 outreach concerning the guidelines,</p> <p>288:10 correct?</p> <p>288:11 A. Correct.</p> <p>288:12 Q. Okay. Do you understand</p> <p>288:13 that to be a part of the educational</p> <p>288:14 outreach?</p> <p>288:15 A. I do, yes.</p>	PK03.127
289:10 - 289:16	<p><b>Kelly, Patrick 05-10-2019 (00:00:15)</b></p> <p>289:10 Q. So it's HDA's practice to</p> <p>289:11 provide webinars to core distributor</p> <p>289:12 members, correct?</p> <p>289:13 A. Yes.</p> <p>289:14 Q. And this is a webinar dated</p> <p>289:15 Friday, February (sic) 14, 2008, agreed?</p> <p>289:16 A. Yes.</p>	PK03.128

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
291:5 - 291:16	<b>Kelly, Patrick 05-10-2019 (00:00:35)</b> 291:5 Q. Okay. It says prescription 291:6 drug abuse. And it talks about increase 291:7 in prescribing for pain, nonmedical 291:8 prescription drug use is up 80 percent 291:9 from 2000. Am I reading that correct? 291:10 A. That's what -- yes. 291:11 Q. And there is some discussion 291:12 about the "Dear Registrant" Rannazzisi 291:13 letters. Some of this we've seen in the 291:14 other presentations, agree? Such as the 291:15 October 31, 2008, one? Or I'm sorry, 291:16 January 31, 2008, one?	PK03.129
291:19 - 291:19	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b> 291:19 THE WITNESS: Yes.	PK03.197
291:21 - 291:24	<b>Kelly, Patrick 05-10-2019 (00:00:10)</b> 291:21 Q. Then you go to Slide 15. It 291:22 tells you the purpose of the industry 291:23 compliance guidelines and the DEA 291:24 communications, agree?	PK03.130
292:3 - 292:3	<b>Kelly, Patrick 05-10-2019 (00:00:01)</b> 292:3 THE WITNESS: Yes.	PK03.131
292:5 - 292:8	<b>Kelly, Patrick 05-10-2019 (00:00:07)</b> 292:5 Q. So, the purpose -- one of 292:6 the purposes is to head off further 292:7 enforcement of regulatory action, agree? 292:8 A. That's what it states.	PK03.132
292:9 - 292:16	<b>Kelly, Patrick 05-10-2019 (00:00:10)</b> 292:9 Q. One of them is to 292:10 demonstrate our members' commitment. 292:11 Do you see that? 292:12 A. Yes. 292:13 Q. Another one says to see 292:14 distributors as part of the solution. 292:15 Do you see that? 292:16 A. Yes.	PK03.174
295:4 - 295:8	<b>Kelly, Patrick 05-10-2019 (00:00:21)</b> 295:4 Q. I'm handing you what's 295:5 marked Exhibit 30. It's an e-mail, 295:6 two-page e-mail with an attachment,	PK03.133

## PK03-Kelly, Patrick - Plaintiffs' Submission

Page/Line	Source	ID
295:13 - 296:2	<p>295:7 one-page attachment, Bates-labeled  295:8 HDA_MDL_000080421 through 423.  <b>Kelly, Patrick 05-10-2019 (00:00:25)</b></p> <p>295:13 Q. Are you familiar with this  295:14 discussion; you were at HDA at this time,  295:15 correct?  295:16 A. I was at HDA at this time,  295:17 yes. I am not familiar with this  295:18 particular e-mail, but I understand the  295:19 correspondence between the communications  295:20 department and -- and Anita Ducca.  295:21 Q. Okay. So Farah Qureshi, am  295:22 I -- am I saying that right?  295:23 A. Yes.  295:24 Q. She's a communications  296:1 manager?  296:2 A. Yes.</p>	PK03.134
296:17 - 296:22	<p><b>Kelly, Patrick 05-10-2019 (00:00:11)</b></p> <p>296:17 Q. Okay. So Farrah's job is to  296:18 draft materials that will be on HDA's  296:19 website?  296:20 A. Yes. And kind of, you know,  296:21 position them and pretty them up for the  296:22 website.</p>	PK03.135
297:7 - 298:22	<p><b>Kelly, Patrick 05-10-2019 (00:01:18)</b></p> <p>297:7 Q. And then Anita Ducca  297:8 provides some comments in this e-mail  297:9 dated Wednesday June 12, 2013. Agree?  297:10 A. Yes.  297:11 Q. And then she actually  297:12 attaches the redline that's -- and the  297:13 redline is what is the second page,  297:14 agree?  297:15 A. Yes, it appears so.  297:16 Q. Okay. So one of Anita's  297:17 comments is, she says, "Although there  297:18 are some examples of what our members do,  297:19 I'm hesitant to include anything like  297:20 that."  297:21 You see that in the third</p>	PK03.136

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297:22 paragraph?

297:23 A. Yes.

297:24 Q. And then she says, "Not all

298:1 our members are doing what HD Smith

298:2 does."

298:3 Do you see that?

298:4 A. Yes.

298:5 Q. "If DEA sees this, which

298:6 they are likely to at some point, they

298:7 may question why all our members aren't

298:8 doing it."

298:9 Do you see that?

298:10 A. Yes.

298:11 Q. "Sort of like how they took

298:12 our ICG and included it in their legal

298:13 filing against Walgreens Distribution

298:14 Center, claiming that there was an

298:15 industry standard that Walgreens should

298:16 have known about and been following."

298:17 Do you see that?

298:18 A. I do.

298:19 Q. There were some frustration

298:20 at HDA that DEA had cited the industry

298:21 compliance guidelines as an industry

298:22 standard and used them against Walgreens?

299:1 - 299:10

**Kelly, Patrick 05-10-2019 (00:00:18)**

PK03.137

299:1 THE WITNESS: I don't know

299:2 that there was frustration. I

299:3 think we were -- we were slightly

299:4 concerned that a document that was

299:5 voluntary guidelines was cited in

299:6 a -- in a proceeding by DEA

299:7 against a non-HD member or non --

299:8 at that point still HDMA or HDA at

299:9 that point. So that was the

299:10 concern.

300:5 - 300:7

**Kelly, Patrick 05-10-2019 (00:00:16)**

PK03.138

300:5 Exhibit 31 is Bates-labeled

300:6 HDA\_MDL\_000155930 through 155946.

300:7 MR. WEINSTEIN: 47 actually.

## PK03-Kelly, Patrick - Plaintiffs' Submission

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301:1 - 301:6	<b>Kelly, Patrick 05-10-2019 (00:00:10)</b> 301:1 Q. Do you have any reason to 301:2 dispute that the statements in here are 301:3 accurate with respect to discussions at 301:4 the board meetings? 301:5 A. No, I have no reason to 301:6 dispute that.	PK03.139
302:13 - 302:15	<b>Kelly, Patrick 05-10-2019 (00:00:22)</b> 302:13 Q. Handing you what's marked as 302:14 Exhibit 32. It's a two-page document 302:15 Bates-labeled HDA_MDL_00081415 and 416.	PK03.140
302:19 - 303:7	<b>Kelly, Patrick 05-10-2019 (00:00:33)</b> 302:19 Q. I just wanted to direct your 302:20 attention to second paragraph on the 302:21 first page. 302:22 "The regulatory affairs 302:23 committee and federal government affairs 302:24 committee told its members that there was 303:1 some consideration about updating the 303:2 guidelines, but ultimately it was decided 303:3 that they would be replaced with a 303:4 statement to the effect that the industry 303:5 is very committed to compliance." 303:6 And there was a draft that 303:7 was exchanged with members, agree?	PK03.141
303:10 - 303:19	<b>Kelly, Patrick 05-10-2019 (00:00:19)</b> 303:10 THE WITNESS: Yes, that's 303:11 what this says. 303:12 BY MR. PIFKO: 303:13 Q. And that's what happened? 303:14 A. I don't recall exactly what 303:15 the process was between the ICGs coming 303:16 down and a statement going up in its 303:17 stead. But again, I have no reason to 303:18 doubt that this process described here is 303:19 accurate.	PK03.142
315:7 - 315:8	<b>Kelly, Patrick 05-10-2019 (00:00:02)</b> 315:7 Q. Handing you what's marked as 315:8 Exhibit 34.	PK03.143
316:9 - 316:16	<b>Kelly, Patrick 05-10-2019 (00:00:24)</b>	PK03.144

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	316:9 Exhibit 34 is an e-mail from John Gray 316:10 dated Friday, April 20, 2012, to Ken 316:11 Couch, Dale Smith, David Neu, Paul 316:12 Julian, Mike Kaufmann, David Moody and 316:13 Ted Scherr, copying Richard Frank from 316:14 HDA's outside counsel. 316:15 Agree? 316:16 A. Yes.	
316:20 - 316:23	<b>Kelly, Patrick 05-10-2019 (00:00:10)</b> 316:20 So at this executive 316:21 committee conference call, there was 316:22 concerns raised by the members again 316:23 about DEA's enforcement activity. Agree?	PK03.145
317:2 - 317:14	<b>Kelly, Patrick 05-10-2019 (00:00:22)</b> 317:2 THE WITNESS: Yes. 317:3 BY MR. PIFKO: 317:4 Q. And so then, there was a 317:5 decision that they needed to plot a 317:6 course going forward as it says in 317:7 Exhibit 31, agree? 317:8 A. Yes, that's what it says. 317:9 Q. Okay. So after that call, 317:10 John Gray says here that he met with 317:11 legal counsel Bob Barnett and Richard 317:12 Cooper from Williams & Connolly in 317:13 Washington DC, agreed? 317:14 A. Yes.	PK03.146
319:2 - 319:22	<b>Kelly, Patrick 05-10-2019 (00:01:01)</b> 319:2 Q. And then the attached, the 319:3 following three pages of Exhibit 34 is 319:4 this document that says, according to the 319:5 e-mail, it's, "DEA options memorandum, 319:6 J. Gray edits," do you see that on the 319:7 first page? On the header of the e-mail, 319:8 that's what the attached document is? 319:9 A. Yes, yes, yes, yes, yes. 319:10 Q. So then it's a memo from 319:11 Mr. Gray to the HDMA executive committee 319:12 dated April 20, 2012. Agree? 319:13 A. Yes.	PK03.147

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319:14 Q. And who is on the executive  
 319:15 committee at this time?  
 319:16 A. At this time it is Ken Couch  
 319:17 from Smith Drug, Dale Smith from  
 319:18 HD Smith, Dave Neu from  
 319:19 AmerisourceBergen, Paul Julian from  
 319:20 McKesson, Mike Kaufmann from Cardinal,  
 319:21 David Moody from North Carolina Mutual  
 319:22 and Ted Scherr from Dakota Drug.

323:4 - 323:22

**Kelly, Patrick 05-10-2019 (00:00:38)**

PK03.148

323:4 Q. Okay. So another thing  
 323:5 Mr. Gray writes in this memo is that  
 323:6 "Paul Barnett and Rich Cooper from  
 323:7 Williams & Connolly felt that the  
 323:8 industry may be better off asserting DEA  
 323:9 actions by taking even stronger  
 323:10 compliance measures."  
 323:11 Do you see that?

323:12 A. Yes.

323:13 Q. Did I read that correctly?

323:14 A. You did.

323:15 Q. Were you part of these  
 323:16 discussions?

323:17 A. I was in this meeting at  
 323:18 Williams & Connolly, yes.

323:19 Q. Okay. And so one of the  
 323:20 recommendations they said is that HDA's  
 323:21 members could avert action by improving  
 323:22 their compliance systems?

324:1 - 324:14

**Kelly, Patrick 05-10-2019 (00:00:13)**

PK03.149

324:1 THE WITNESS: That's -- I  
 324:2 mean, it says that they felt they  
 324:3 were better off averting DEA  
 324:4 actions by taking even stronger  
 324:5 compliance measures. That's  
 324:6 what's written in the memo.  
 324:7 BY MR. PIFKO:  
 324:8 Q. And that's what was  
 324:9 discussed at the meeting? You said you  
 324:10 were there?

## PK03-Kelly, Patrick - Plaintiffs' Submission

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	324:11 A. I was there, yes.	
	324:12 Q. And that's consistent with	
	324:13 what was discussed there?	
	324:14 A. Yes.	
326:10 - 327:11	<b>Kelly, Patrick 05-10-2019 (00:00:48)</b>	PK03.150
	326:10 Q. Okay. Another potential	
	326:11 action, again going to Page 2 of the	
	326:12 notes, is, "Seek guidance from a	
	326:13 well-respected public relations firm to	
	326:14 improve industry image."	
	326:15 This was something else that	
	326:16 was considered?	
	326:17 A. Yes.	
	326:18 Q. Did you ever move forward	
	326:19 with that option?	
	326:20 A. We did.	
	326:21 Q. And who did you retain?	
	326:22 A. Processwise, after this	
	326:23 meeting, we've been through -- we've been	
	326:24 engaged with several public relations	
	327:1 firm. But I think this one led to an	
	327:2 initial engagement with APCO.	
	327:3 Q. And they developed the	
	327:4 crisis playbook, right?	
	327:5 A. That -- yes, that was their	
	327:6 development, yes. I don't know if that's	
	327:7 the specific name of it. But it was --	
	327:8 Q. But you're familiar with	
	327:9 that document?	
	327:10 A. Yes, that they developed,	
	327:11 yes.	
413:23 - 414:1	<b>Kelly, Patrick 05-10-2019 (00:00:05)</b>	PK03.198
	413:23 Q. I'm going to turn your	
	413:24 attention back to Exhibit 1, the subpoena	
	414:1 with the topics. Are you there?	
414:2 - 418:12	<b>Kelly, Patrick 05-10-2019 (00:03:13)</b>	PK03.187
	414:2 A. I am.	
	414:3 Q. Okay. Topic Number 3 is	
	414:4 your lobbying activities related to the	
	414:5 manufacture, marketing, advertising and	

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414:6 distribution of opioids or opioid  
414:7 products.  
414:8 Do you see that?  
414:9 A. I do.  
414:10 Q. Do you understand yourself  
414:11 to be -- have been designated to talk  
414:12 about that topic here today?  
414:13 A. I do.  
414:14 Q. We talked about Topic 4  
414:15 already.  
414:16 Topic Number 5: Your  
414:17 advocacy or legal support for any  
414:18 defendant, including but not limited to,  
414:19 amicus curiae briefs or any -- or other  
414:20 legal documents prepared by you in  
414:21 support of any defendant.  
414:22 Do you see that?  
414:23 A. I do.  
414:24 Q. Do you understand yourself  
415:1 to be designated to talk on that topic  
415:2 today?  
415:3 A. I do.  
415:4 Q. Topic Number 6: The nature,  
415:5 scope and identity of any conferences,  
415:6 seminars or webinars you have sponsored,  
415:7 promoted or organized where the duty to  
415:8 prevent diversion and identify and report  
415:9 suspicious orders was included among the  
415:10 topics of discussion.  
415:11 Do you see that?  
415:12 A. I do.  
415:13 Q. Do you understand yourself  
415:14 to be designated to talk on that topic  
415:15 today?  
415:16 A. I do.  
415:17 Q. Topic Number 7:  
415:18 Communications with the DEA or any state  
415:19 or federal government agency regarding  
415:20 the diversion or suspicious orders of  
415:21 opioids or opioid products, including but

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415:22 not limited to, the attendance,  
415:23 participation in, presentations given by  
415:24 the DEA at your conferences, seminars, or  
416:1 webinars regarding advice, direction,  
416:2 guidance or instruction regarding the  
416:3 duty to prevent diversion and identify  
416:4 and report suspicious orders.  
416:5 Do you understand yourself  
416:6 to be designated to talk on that topic  
416:7 today?  
416:8 A. I do.  
416:9 Q. Topic Number 8: Any  
416:10 communications efforts, activities,  
416:11 initiatives or work performed by you  
416:12 regarding quotas set by the DEA,  
416:13 including increases to or maintenance of  
416:14 the quotas.  
416:15 Do you understand yourself  
416:16 to be designated to talk on that topic  
416:17 today?  
416:18 A. Yes.  
416:19 Q. The scope -- Topic  
416:20 Number 12: The scope and nature of any  
416:21 discussions of any council, committee,  
416:22 task force or working group of the HDA  
416:23 concerning opioids.  
416:24 Do you see that?  
417:1 A. I do.  
417:2 Q. Do you understand yourself  
417:3 to be designated to talk on that topic  
417:4 today?  
417:5 A. I do.  
417:6 Q. Topic Number 13: The scope  
417:7 and nature of any discussions of any  
417:8 council, committee, task force, or  
417:9 working group of the HDA concerning  
417:10 diversion of controlled substances.  
417:11 Do you see that?  
417:12 A. I do.  
417:13 Q. Do you understand yourself

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	417:14 to be designated to talk on that topic	
	417:15 today?	
	417:16 A. I do.	
	417:17 Q. What did you do to prepare	
	417:18 to testify on those topics?	
	417:19 A. I met with counsel several	
	417:20 days in the last couple days and then	
	417:21 previously when we thought this was going	
	417:22 to be scheduled earlier, or later in	
	417:23 2018. So probably four or five meetings	
	417:24 with counsel and staff.	
	418:1 Q. Okay. I was going to ask	
	418:2 you. Besides counsel, did you meet with	
	418:3 any staff members?	
	418:4 A. I did. I met with Anita	
	418:5 Ducca primarily to understand the period	
	418:6 of time I was not at HDA.	
	418:7 Q. And did she provide any	
	418:8 documents to you?	
	418:9 A. Other than the documents	
	418:10 that were produced.	
	418:11 Q. So she provided documents to	
	418:12 you that were produced?	
418:15 - 418:15	<b>Kelly, Patrick 05-10-2019 (00:00:00)</b>	PK03.199
	418:15 THE WITNESS: No. Counsel	
418:16 - 420:1	<b>Kelly, Patrick 05-10-2019 (00:00:52)</b>	PK03.200
	418:16 provided the documents.	
	418:17 BY MR. PIFKO:	
	418:18 Q. Okay. So when you	
	418:19 understood you were going to be	
	418:20 designated to come speak for the HDA at	
	418:21 this deposition, counsel provided you	
	418:22 with documents that had been produced in	
	418:23 the litigation?	
	418:24 A. That's correct.	
	419:1 Q. Okay. And when you met with	
	419:2 Ms. Ducca, did we go over any of those	
	419:3 documents?	
	419:4 A. We did.	
	419:5 Q. Okay. Did you review the	

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419:6 documents on your own time without

419:7 anybody?

419:8 A. I did not.

419:9 Q. Okay. Who else besides

419:10 Ms. Ducca from the staff did you meet

419:11 with?

419:12 A. Our general counsel

419:13 participated in the meetings as well.

419:14 Q. Okay. Anyone else?

419:15 A. No.

419:16 Q. About how many hours did you

419:17 meet with Ms. Ducca?

419:18 A. Over the course, probably

419:19 eight -- between eight and ten hours.

419:20 Q. And you felt, based on those

419:21 discussions and the review of documents,

419:22 that you had adequate understanding to

419:23 testify on those topics I just read to

419:24 you?

420:1 A. I do.

420:15 - 420:24

**Kelly, Patrick 05-10-2019 (00:00:33)**

PK03.152

420:15 Q. Handing you what's marked as

420:16 Exhibit 51.

HDA-KELLY-  
51.1

420:17 And while you are looking --

420:18 go ahead and take your time to look at

HDA-KELLY-  
51.1.1

420:19 that, but then I also want you to pull

420:20 out Exhibit 11 which goes with

420:21 Exhibit 51.

420:22 For the record, Exhibit 51

420:23 is a three-page document Bates-labeled

420:24 CAH\_MDL2804\_02201918 through 1920.

421:6 - 422:2

**Kelly, Patrick 05-10-2019 (00:00:51)**

PK03.153

421:6 Q. So you recall, when I showed

421:7 you Document 11 and I asked you if you

421:8 had an understanding about the date of

421:9 when the National Wholesale Druggists'

421:10 Association suspicious order monitoring

421:11 system, which is Exhibit 11, what the

421:12 date of that document was, do you recall

421:13 that discussion?

## PK03-Kelly, Patrick - Plaintiffs' Submission

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421:14 A. I recall that discussion,

421:15 yes.

421:16 Q. Okay. Well, Exhibit 51 is a

421:17 series of letters from the DEA concerning

421:18 the National Wholesale Druggists'

421:19 Association's suspicious order monitoring

421:20 system. And if you see, the first page

421:21 of Exhibit 51 is stamped April 27, 1984.

HDA-KELLY-  
51.1.2

421:22 Do you see that?

421:23 A. I do.

421:24 Q. Does that refresh your

422:1 recollection that Exhibit 11 is from

422:2 approximately in the early '80s?

422:5 - 424:23

**Kelly, Patrick 05-10-2019 (00:02:12)**

PK03.154

422:5 THE WITNESS: I will --

422:6 again, I have not seen either of

422:7 these documents. I will take it

422:8 at face value that that was when

422:9 this document was prepared.

422:10 BY MR. PIFKO:

422:11 Q. Okay. Well, Exhibit 51 is a

422:12 letter from Thomas Gitchel, acting chief

422:13 diversion operations section of the DEA,

422:14 correct?

HDA-KELLY-  
51.2.1

422:15 A. Yes.

422:16 Q. And it's dated April 27,

422:17 1984, correct?

HDA-KELLY-  
51.1.2

422:18 A. Yes.

422:19 Q. And it's to Ronald J.

HDA-KELLY-  
51.1.3

422:20 Streck, vice president of government

422:21 affairs, National Wholesale Druggists'

422:22 Association.

422:23 That's a predecessor entity

422:24 of HDA, correct?

423:1 A. That's correct.

423:2 Q. Do you know who Mr. Streck

423:3 is?

423:4 A. Mr. Streck became at one

423:5 point the CEO of the NWDA.

423:6 Q. Okay. Do you know around

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423:7 the time that was?

423:8 A. I do not know when he --

423:9 Mr. Gray did succeed him as the CEO.

423:10 Q. Okay. Mr. Gray was

423:11 immediately after him?

423:12 A. Immediately after him, yes.

423:13 Q. Okay. So this document

423:14 says, the second full paragraph, "The

423:15 NWDA's draft format for suspicious order

423:16 monitoring system provides an excellent

423:17 framework for distributor" --

423:18 "distributor registrants to design and

423:19 operate a system to disclose to

423:20 registrants suspicious orders of

423:21 controlled substances."

423:22 Do you see that?

423:23 A. I do.

423:24 Q. And it says, "Draft format

424:1 for a suspicious order monitoring

424:2 system." And Exhibit 11 says,

424:3 "Suspicious order monitoring system,"

424:4 correct?

424:5 A. It does.

424:6 Q. Okay. Then on the bottom of

424:7 that same paragraph, Mr. Gitchel says in

424:8 the letter to Mr. Streck, "As previously

424:9 discussed, an after-the-fact computer

424:10 printout of sales data does not relieve a

424:11 registrant of its responsibility to

424:12 report excessive or suspicious orders

424:13 when discovered."

424:14 Do you see that?

424:15 A. I do.

424:16 Q. And then he says, "I'm

424:17 enclosing a copy of your draft with my

424:18 pen and ink changes."

424:19 Do you see that?

424:20 A. I do.

424:21 Q. Do you agree -- any reason

424:22 to dispute that the NWDA received this

HDA-KELLY-  
51.1.4

HDA-KELLY-  
11.1.1

HDA-KELLY-  
51.1.5

HDA-KELLY-  
51.1.6

## PK03-Kelly, Patrick - Plaintiffs' Submission

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425:2 - 425:7	<p>424:23 document?</p> <p><b>Kelly, Patrick 05-10-2019 (00:00:07)</b></p> <p>425:2 THE WITNESS: No reason to</p> <p>425:3 dispute that they received a pen</p> <p>425:4 and ink draft marked-up version.</p> <p>425:5 BY MR. PIFKO:</p> <p>425:6 Q. And this letter from DEA,</p> <p>425:7 correct?</p>	PK03.155
425:10 - 425:16	<p><b>Kelly, Patrick 05-10-2019 (00:00:16)</b></p> <p>425:10 THE WITNESS: No reason to</p> <p>425:11 dispute that.</p> <p>425:12 BY MR. PIFKO:</p> <p>425:13 Q. Based on your understanding</p> <p>425:14 of the HDA and as a designee under Rule</p> <p>425:15 30(b)(6), do you believe this would have</p> <p>425:16 been provided to HDA's members?</p>	PK03.156
425:19 - 428:2	<p><b>Kelly, Patrick 05-10-2019 (00:01:55)</b></p> <p>425:19 THE WITNESS: Again, I don't</p> <p>425:20 know what capabilities were back</p> <p>425:21 in 1984. I would imagine it was</p> <p>425:22 reported at some point to HDA</p> <p>425:23 members.</p> <p>425:24 BY MR. PIFKO:</p> <p>426:1 Q. Okay. In the first</p> <p>426:2 paragraph --</p> <p>426:3 A. Or NWDA members.</p> <p>426:4 Q. In the first paragraph he</p> <p>426:5 says, "I want to thank" -- "I want to</p> <p>426:6 take this opportunity to thank you,</p> <p>426:7 Mr. Streck, and then Mr. David Prins,</p> <p>426:8 from Twin City Wholesale, and Mr. Robert</p> <p>426:9 Bone from Bergen Brunswig for meeting</p> <p>426:10 with David Walkup and me on April 13,</p> <p>426:11 1984."</p> <p>426:12 Do you see that?</p> <p>426:13 A. I do.</p> <p>426:14 Q. So based on this, it appears</p> <p>426:15 some of the members in addition to</p> <p>426:16 Mr. Streck met with the DEA about the</p> <p>426:17 suspicious order monitoring system,</p>	<p>PK03.157</p> <p>HDA-KELLY- 51.1.7</p>

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426:18 correct?

426:19 A. It would appear so, yes.

426:20 Q. Then the third page of

426:21 Exhibit 51 is another letter to

426:22 Mr. Streck from Thomas Gitchel.

426:23 Do you see that?

426:24 A. I do.

427:1 Q. And it appears to be dated

427:2 May 16, 1984.

427:3 Do you see that?

427:4 A. I do.

427:5 Q. In the letter from

427:6 Mr. Gitchel, he says at the bottom of the

427:7 first full paragraph, "However, I want to

427:8 make it clear that the submission of

427:9 monthly printout of after-the-fact sales

427:10 will not relieve a registrant from the

427:11 responsibility of reporting excessive or

427:12 suspicious orders. DEA has interpreted

427:13 orders to mean prior to shipment."

427:14 Do you see that?

427:15 A. I do.

427:16 Q. And that's consistent with

427:17 the language that we discussed on Page

427:18 seven of Exhibit 11 where it says, "DEA

427:19 has interpreted orders to mean prior to

427:20 shipment."

427:21 Do you see that?

427:22 A. I do.

427:23 Q. Do you agree that it's --

427:24 this DEA letter from 1984 is consistent

428:1 with that language in the NWDA's

428:2 suspicious order monitoring system?

428:5 - 428:10

**Kelly, Patrick 05-10-2019 (00:00:12)**

428:5 THE WITNESS: It appears to

428:6 be the same statement, yes.

428:7 BY MR. PIFKO:

428:8 Q. Do you believe that this May

428:9 16th, 1984 letter would have been shared

428:10 with the NWDA's members?

HDA-KELLY-  
51.3

HDA-KELLY-  
51.3.1

HDA-KELLY-  
51.3.2

PK03.158

clear

## PK03-Kelly, Patrick - Plaintiffs' Submission

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428:13 - 428:22	<b>Kelly, Patrick 05-10-2019 (00:00:17)</b> 428:13 THE WITNESS: Again, I can't 428:14 say for certain. I would imagine 428:15 that it was. As correspondence 428:16 like this would technically be 428:17 shared with the membership. 428:18 BY MR. PIFKO: 428:19 Q. And again, because HDA and 428:20 its predecessor entities would act on 428:21 behalf of the members, not for its own 428:22 interest, correct?	PK03.159
429:1 - 429:3	<b>Kelly, Patrick 05-10-2019 (00:00:03)</b> 429:1 THE WITNESS: Most -- yes, 429:2 as most trade associations do, on 429:3 behalf of their members.	PK03.160
441:7 - 441:19	<b>Kelly, Patrick 05-10-2019 (00:00:20)</b> 441:7 Q. And I believe you testified 441:8 earlier that the -- the regulatory 441:9 affairs committee created the -- HDA's 441:10 industry compliance guidelines; is that 441:11 correct? 441:12 A. That's -- that's correct. 441:13 Q. The industry compliance 441:14 guidelines are guidelines for 441:15 distributors; is that right? 441:16 A. That's correct. 441:17 Q. They are not meant to be 441:18 implemented by manufacturers? 441:19 A. That is correct.	PK03.161

Plaintiffs Affirmative Designations = 01:11:55

Defense Completeness Counters = 00:03:53

**Total Time = 01:15:48**

**Documents Shown**

HDA-KELLY-11

HDA-KELLY-51